

Research Toward a Cure October 16, 2020

Table 1. Current Clinical Trials

Trial	Trial Registry Identifier(s)	Sponsor(s)	Phase	Estimated End Date/Interim Results
ADOPTIVE IMMUNOTHERAPY				
alloRESIST: Evaluate the safety, immunologic, and virologic responses of donor derived HIV-specific T-cells in HIV+ individuals following allogeneic bone marrow transplantation	NCT04248192 (not yet open for enrollment)	Catherine Bollard, Children's Research Institute	Phase I	April 2024
HST-NEETs: HIV-1 specific T-cells for HIV-infected individuals	NCT03485963	Children's Research Institute	Phase I	December 2021
ANTIBODIES				
10-1074-LS + 3BNC117-LS in primary HIV infection	NCT04319367 (not yet open for enrollment)	Imperial College London	Phase II	October 2024
UB-421 (antibody inhibitor of HIV binding to CD4 receptors)	NCT04404049 (not yet open for enrollment)	UBP Greater China (Shanghai) Co., Ltd	Phase II	June 2024
UB-421	NCT03743376	United BioPharma	Phase II	December 2020
vedolizumab (anti- $\alpha_4\beta_7$ integrin antibody)	NCT03577782	Hospitales Universitarios Virgen del Rocío	Phase II	May 2020
vedolizumab	NCT03147859	Ottawa Hospital Research Institute	Phase II	December 2021 CROI 2019, Abstract 393 , Webcast
PGT121 + VRC07-523LS +/- PGDM1400	NCT03721510	International AIDS Vaccine Initiative	Phase I/Ila	November 2020
VRC01 (broadly neutralizing antibody) in infants	NCT03208231 (closed to enrollment)	NIAID	Phase I/II	February 2021
VRC01LS + 10-1074 (broadly neutralizing antibodies) in early-treated children	NCT03707977	NIAID	Phase I/II	October 2021
10-1074-LS + 3BNC117-LS (long-acting broadly neutralizing antibodies)	NCT03554408 (closed to enrollment)	Rockefeller University	Phase I	June 2021
3BNC117 + 10-1074 (broadly neutralizing antibodies)	NCT03571204	NIAID	Phase I	June 2021
3BNC117 + 10-1074	NCT03526848	Rockefeller University	Phase I	April 2022

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ANTIBODIES (Cont.)				
3BNC117-LS	NCT03254277 (closed to enrollment)	Rockefeller University	Phase I	December 2020
3BNC117-LS + 10-1074-LS in viremic HIV+ individuals	NCT04250636	Rockefeller University	Phase I	February 2022
AAV8-VRC07 (broadly neutralizing antibody delivered by AAV vector)	NCT03374202	NIAID	Phase I	March 2020 CROI 2020, Abstract 41LB , Webcast
Elipovimab (formerly GS-9722; PGT121-derived broadly neutralizing antibody)	GS-US-420-3902 Adisinsight entry (not listed in clinicaltrials.gov)	Gilead Sciences	Phase I	N/A CROI 2020, Abstract 39 , Webcast
SAR441236 (tri-specific broadly neutralizing antibody)	NCT03705169	NIAID	Phase I	February 2022
VRC01 + 10-1074	NCT03831945	NIAID	Phase I	March 2024
VRC01 in acute HIV infection	NCT02591420	NIAID	Phase I	March 2021
ANTI-INFLAMMATORY				
canakinumab (IL-1 β inhibitor)	NCT02272946	University of California, San Francisco	Phase II	December 2022 J Am Coll Cardiol. 2018 Dec 4;72(22):2809-2811. CROI 2017, Abstract 126 , Webcast
CD24Fc (human CD24 extracellular domain and human IgG1 Fc fusion protein)	NCT03960541	Oncolimmune, Inc.	Phase II	October 2022

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ANTI-PROLIFERATIVE				
mycophenolate mofetil (MMF)	NCT03262441 (closed to enrollment)	Fred Hutchinson Cancer Research Ctr	Phase I	August 2021 CROI 2020, Abstract 340
ANTIRETROVIRAL THERAPY				
doravirine concentrations and antiviral activity in cerebrospinal fluid	NCT04079452 (not yet open for enrollment)	Fundacio Lluita Contra la SIDA	Phase III	October 2020
IDOLTIB: Impact of dolutegravir + lamivudine simplification on HIV-1 reservoirs	NCT04034862 (not yet open for enrollment)	University of Liege	Phase III	March 2022
CANNABINOIDS				
TN-CT11LM, TN-TC19LM oral capsules	NCT03550352 (not yet open for enrollment)	McGill University Health Center	Phase II	December 2019
COMBINATIONS				
Perturbing of HIV reservoir with immune stimulation: Fluarix, Pneumovax vaccines	NCT02707692 (closed to enrollment)	University of California, San Diego	Not listed	January 2021
MVA.HTI + ChAdOx1.HTI therapeutic vaccines + vesatolimod (TLR7 agonist)	NCT04364035	Aelix Therapeutics	Phase IIa	December 2022
ROADMAP: romidepsin + 3BNC117	NCT02850016 (closed to enrollment)	Rockefeller University	Phase IIa	December 2020 CROI 2020, Abstract 38 , Webcast
TITAN: lefotolimod + 3BNC117 + 10-1074 (TLR9 agonist + broadly neutralizing antibodies)	NCT03837756	University of Aarhus	Phase IIa	February 2021
eCLEAR: romidepsin + 3BNC117	NCT03041012 (closed to enrollment)	Aarhus University Hospital	Phase II	June 2021
MVA HIV-B +/- vedolizumab (viral vector vaccine +/- anti- $\alpha_4 \beta_7$ integrin antibody)	NCT04120415 (not yet open for enrollment)	French National Agency for Research on AIDS and Viral Hepatitis (Inserm/ANRS)	Phase II	December 2022

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COMBINATIONS (Cont.)				
Research in Viral Eradication of HIV Reservoirs (RIVER): ART, ChAdV63.HIVcons & MVA.HIVcons vaccines, vorinostat	NCT02336074 UK CPMS18010 (closed to enrollment)	Imperial College London	Phase II	November 2022 Lancet. 2020 Mar 14;395(10227):888-898 AIDS 2018, Abstract TUAA0202LB (slides , video)
vorinostat +/- tamoxifen in postmenopausal women	NCT03382834 (closed to enrollment)	NIAID	Phase II	June 2023 CROI 2020, Abstract 333 , Webcast HIV Persistence Workshop 2019, Abstract OP 3.2 (see abstract book)
HIVARNA01.3, MVA vector HIV vaccine, 10-1074, romidepsin, HIVACAR01 (personalized HIV RNA vaccine)	NCT03619278 (not yet open for enrollment)	David Garcia Cinca	Phase I/IIa	July 2021
IMPAACT P1115 v2.0: Very early intensive treatment of HIV-infected infants to achieve HIV remission (ART +/- VRC01)	NCT02140255	IMPAACT	Phase I/II	December 2031
panobinostat + pegylated interferon-alpha2a	NCT02471430	Massachusetts General Hospital	Phase I/II	December 2020 CROI 2020, Abstract 341
Therapeutic conserved element DNA vaccine (IL-12 adjuvanted p24CE), MVA vaccine boost (MVA/HIV62B), TLR9 agonist (lefilolimod) and broadly neutralizing antibodies (VRC07-523LS + 10-1074)	NCT04357821	UCSF	Phase I/II	December 2024

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COMBINATIONS (Cont.)				
Adoptive transfer of haploididential NK cells and N-803	NCT03899480	University of Minnesota - Clinical and Translational Science Institute	Phase I	September 2020
CD4-ZETA gene-modified T cells +/- interleukin-2 (IL-2)	NCT01013415 (closed to enrollment)	University of Pennsylvania	Phase I	December 2021 CROI 2020, Abstract 337 , Webcast Mol Ther. 2002 Jun;5(6):788-97
Chidamide + CAR-T or TCR-T cell therapy	NCT03980691	Guangzhou 8th People's Hospital	Phase I	December 2021
HVRRICANE: HIVIS DNA + MVA-CMDR vaccines +/- TLR4 agonist	NCT04301154 (not yet open for enrollment)	PENTA Foundation	Phase I	September 2021
N-803 (recombinant human super agonist interleukin-15 complex) +/- VRC07-523LS + 10-1074	NCT04340596 (not yet open for enrollment)	NIAID	Phase I	June 2023
peginterferon alfa-2b + 3BNC117 + 10-1074 (BEAT-2)	NCT03588715	Wistar Institute	Phase I	June 2022
VRC07-523LS + vorinostat	NCT03803605	University of North Carolina, Chapel Hill	Phase I	July 2022
vorinostat + HXTC: HIV 1 antigen expanded specific T cell therapy	NCT03212989 (closed to enrollment)	Julia Sung, MD, University of North Carolina, Chapel Hill	Phase I	June 2021
CYTOKINES				
interleukin-2 (IL-2)	NCT03308786	Case Western Reserve University	Phase II	December 2021
N-803 in acute HIV infection	NCT04505501 (not yet open for enrollment)	Thai Red Cross AIDS Research Centre	Phase II	August 2022
DUAL-AFFINITY RE-TARGETING (DART) MOLECULES				
MGD014	NCT03570918	MacroGenics	Phase I	October 2021

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GENE THERAPIES				
Cal-1: Dual anti-HIV gene transfer construct	NCT02390297 (closed to enrollment)	Calimmune	Phase I/II	October 2031 CROI 2020, Abstract 338
SB-728-T (autologous T cells gene-modified to disrupt CCR5 receptor expression)	NCT03666871	Case Western Reserve University	Phase I/II	February 2024
AGT103-T (gene-modified HIV-specific CD4 T cells)	NCT04561258 (not yet open for enrollment)	American Gene Technologies International Inc.	Phase I	September 2022
CD4 CAR + SB-728mR modified T cells	NCT03617198 (closed to enrollment)	University of Pennsylvania	Phase I	December 2025
Chimeric Antigen Receptor (CAR)-T cell therapy	NCT03240328	Guangzhou 8th People's Hospital	Phase I	December 2021
Long-term follow-up of HIV+ participants exposed to SB-728-T or SB-728mR-T	NCT04201782 (enrolling by invitation only)	Sangamo Therapeutics	Phase I	December 2031
SB-728mR-HSPC (autologous hematopoietic stem/progenitor cells genetically modified at the CCR5 gene)	NCT02500849 (closed to enrollment)	City of Hope Medical Center	Phase I	April 2022
shRNA-modified CD34+ cells	NCT03517631	Shanghai Public Health Clinical Center	Phase I	December 2020
Anti-gp120 CAR-T cells (autologous T cells gene-modified to express a chimeric antigen receptor targeting HIV gp120)	ChiCTR-OPN-17013068 (not yet open for enrollment)	Jinyintan Hospital of WuHan	Phase 0	December 2018
GENE THERAPIES FOR HIV-POSITIVE PEOPLE WITH CANCERS				
CRISPR CCR5 modified CD34+ cells	NCT03164135	307 Hospital of PLA (Affiliated Hospital of Academy to Military Medical Sciences)	Not listed	May 2021 N Engl J Med. 2019 Sep 11
Stem cells gene-modified with Cal-1	NCT03593187	Assistance Publique - Hôpitaux de Paris	Phase I/II	January 2024 Mol Ther Methods Clin Dev. 2019 Feb 26;13:303-309

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GENE THERAPIES FOR HIV-POSITIVE PEOPLE WITH CANCERS (Cont.)				
Stem cells gene-modified with CCR5 shRNA/TRIM5alpha/TAR decoy	NCT02797470	AIDS Malignancy Consortium	Phase I/II	June 2036
Stem cells gene-modified to encode multiple anti-HIV RNAs (rHIV7-shl-TAR-CCR5RZ)	NCT02337985 (closed to enrollment)	City of Hope Medical Center	Phase I	June 2022
Stem cells gene-modified to encode multiple anti-HIV RNAs (rHIV7-shl-TAR-CCR5RZ) + busulfan	NCT01961063 (closed to enrollment)	City of Hope Medical Center	Phase I	June 2031
GONADOTROPIN-RELEASING HORMONE (GnRH) AGONISTS				
tripotorelin acetate depot	NCT03536234	Immune System Regulation AB	Phase II	December 2020
HORMONES				
somatotropin (human growth hormone)	NCT03091374	McGill University Health Center	Phase II	December 2020
IMAGING STUDIES				
Imaging immune activation in HIV by PET-MR	NCT03684655	University of California, San Francisco	Phase I	June 2021
Radiolabeled VRC01	NCT03729752	University of California, San Francisco	Phase I	October 2020 CROI 2020, Abstract 72 , Webcast
IMMUNE CHECKPOINT INHIBITORS				
durvalumab (anti-PD-L1 antibody) in solid tumors	NCT03094286 (closed to enrollment)	Spanish Lung Cancer Group	Phase II	April 2022 Journal of Clinical Oncology 37, no. 15 suppl (May 20, 2019) 2501-2501.
budigalimab (anti-PD-1 antibody)	NCT04223804	AbbVie	Phase Ib	July 2022

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IMMUNE CHECKPOINT INHIBITORS (Cont.)				
nivolumab (anti-PD-1 antibody) + ipilimumab (anti-CTLA-4 antibody) in treating patients with advanced HIV associated solid tumors	NCT02408861	National Cancer Institute (NCI)	Phase I	July 2022 December 2020 HIV Persistence Workshop 2019, Abstract OP 5.5 (see abstract book) Journal of Clinical Oncology 36, no. 15 suppl
pembrolizumab (anti-PD-1 antibody) in treating patients with HIV and relapsed, refractory, or disseminated malignant neoplasms	NCT02595866	National Cancer Institute (NCI)	Phase I	July 2021 JAMA Oncol. 2019 Jun 2 CROI 2019, Abstract 27 , Webcast CROI 2018, Poster abstract 656LB
pembrolizumab (anti-PD-1 antibody) single dose	NCT03239899	National Institute of Neurological Disorders and Stroke (NINDS)	Phase I	December 2021
LATENCY-REVERSING AGENTS				
valproic acid + pyrimethamine	NCT03525730	Erasmus Medical Center	Phase I/II	April 2020
arsenic trioxide	NCT03980665	Guangzhou 8th People's Hospital	Phase I	December 2021
Euphorbia kansui	NCT04503928 (not yet open for enrollment)	Shanghai Public Health Clinical Center	Phase I	December 2022
Kansui (traditional Chinese medicine containing ingenols)	NCT02531295 (Suspended - temporary pause on non-COVID clinical trial recruitment at study site)	UCSF	Phase I	December 2020

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mTOR INHIBITORS				
metformin	NCT04500678	University of Hawaii	Phase II/III	December 2022
PROTEASOME INHIBITORS				
ixazomib	NCT02946047 (closed to enrollment)	Mayo Clinic	Phase I	September 2020
STEM CELL TRANSPLANTATION				
HIVECT: HIV eradication through cord-blood transplantation	NCT02923076	Puerta de Hierro University Hospital	N/A	December 2018
<u>IMPAACT P1107</u> : Cord blood transplantation using CCR5-Δ32 donor cells for the treatment of HIV and underlying disease	NCT02140944	International Maternal Pediatric Adolescent AIDS Clinical Trials Group (IMPAACT)	N/A	March 2023 ASH 2018, <u>Abstract 2184</u>
Cord blood transplant with OTS for the treatment of HIV+ hematologic cancers	NCT04083170 (not yet open for enrollment)	Fred Hutchinson Cancer Research Center	Phase II	December 2022
HLA-mismatched unrelated donor bone marrow transplantation	NCT02793544 (closed to enrollment)	Center for International Blood and Marrow Transplant Research	Phase II	April 2020
STIMULANTS				
EMRLHD: Effect of methamphetamine on residual latent HIV disease study	NCT03825536	University of California, San Francisco	Phase IV	August 2023
THERAPEUTIC VACCINES				
p24CE1/2 + p55 ^{gag} conserved-element DNA vaccines	NCT03560258 (closed to enrollment)	NIAID	Phase I/II	February 2021
PENNVAx-GP or INO-6145 + IL-12 DNA adjuvant (INO-9012) (DNA vaccines)	NCT03606213	Steven Deeks, UCSF	Phase I/II	December 2022
Ad26.Mos4.HIV + MVA-Mosaic or clade C gp140 + mosaic gp140 (viral vector vaccines + proteins)	NCT03307915 (closed to enrollment)	Janssen Vaccines & Prevention B.V.	Phase I	December 2021
DC-HIV04: a1DC + inactivated whole autologous HIV, a1DC + conserved HIV peptides	NCT03758625	Sharon Riddler, University of Pittsburgh	Phase I	May 2022

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THERAPEUTIC VACCINES (Cont.)				
DNA.HTI + MVA.HTI + ChAdOx1.HTI (DNA + viral vector vaccines) (ATI extension)	NCT04385875	Fundacio Lluita Contra la SIDA	Phase I	June 2022
DNA.HTI + MVA.HTI + ChAdOx1.HTI (DNA + viral vector vaccines)	NCT03204617 (closed to enrollment)	Aelix Therapeutics	Phase I	March 2021
MVA.tHIVconsV3 +/- MVA.tHIVconsV4 (viral vector vaccines)	NCT03844386	University of North Carolina, Chapel Hill	Phase I	July 2021
TREATMENT INTENSIFICATION/EARLY TREATMENT				
P25-INACTION: Implication for strategies of long term control of viral replication in patients with primary HIV infection	NCT04225325	Adriano Lazzarin, MD	Phase IV	June 2021
Antiretroviral regime for viral eradication in newborns	NCT02712801	National Center for Women and Children's Health, China CDC	Phase IV	December 2020
DGVTAf: Immediate initiation of antiretroviral therapy during "hyperacute" HIV infection	NCT02656511	UCSF	Phase IV	April 2023
AAHIV: Antiretroviral therapy for acute HIV infection	NCT00796263	South East Asia Research Collaboration with Hawaii	Phase III	June 2033 See supplemental references page
tenofovir/emtricitabine + dolutegravir or tenofovir/emtricitabine + darunavir/cobicistat	NCT02987530 (closed to enrollment)	Inserm-ANRS	Phase III	December 2019

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TREATMENT INTENSIFICATION/EARLY TREATMENT (Cont.)				
EIT: Early infant HIV treatment in Botswana	NCT02369406	Harvard School of Public Health	Phase II/III	May 2021 Clin Infect Dis. 2020 Jan 12. [Epub ahead of print] Sci Transl Med. 2019 Nov 27;11(520). pii: eaax7350 CROI 2019, Poster abstract 826 CROI 2018, Abstract 136, Webcast
EARLIER: Early ART to limit infection and establishment of reservoir	NCT02859558 (closed to enrollment)	AIDS Clinical Trials Group	Phase II	May 2021

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Table 2. Observational Studies

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2000HIV: 2000 HIV Human Functional Genomics Partnership Program	NCT03994835	Radboud University	N/A	December 2023
Accurate staging of immuno-virological dynamics during acute HIV infection (ACS)	NCT03449706	University Hospital, Ghent	N/A	January 2023
Analytic treatment interruption (ATI) to assess HIV cure	NCT02437526 (enrolling by invitation only)	Mayo Clinic	N/A	May 2025 PLoS Med. 2017 Nov 28;14(11):e1002461.
ANRS CO24 OncoVIHAC: Immune checkpoint inhibitors in HIV+ individuals with cancers	NCT03354936	Inserm-ANRS	N/A	June 2022
ANRS EP63: A chronological study of the formation of HIV cellular reservoirs through the expression of surface markers on CD4+ T lymphocytes, including CD32a	NCT03298360	Inserm-ANRS	N/A	June 2020
ATGALIG-HIV: Study of autophagy and the effects of GALIG gene products in HIV-1+ patients on antiretroviral therapy since primary infection, chronic phase, or never treated	NCT04160455	Centre Hospitalier Régional d'Orléans	N/A	November 2029
Biomarkers to predict time to plasma HIV RNA rebound (ACTG A5345)	NCT03001128	AIDS Clinical Trials Group	N/A	September 2020 AIDS 2020, Abstract PDB0102
CLEAC: Comparison of late versus early antiretroviral therapy in HIV-infected children	NCT02674867 (closed to enrollment)	Inserm-ANRS	N/A	June 2019 AIDS 2018, Abstract WEAB0208LB (slides)
CODEX (the “Extreme” cohort, ANRS CO21)	NCT01520844	Inserm-ANRS	N/A	September 2023 See supplemental references page
Developing a functional cure for HIV disease: Clinical specimen collection from HIV+ individuals	NCT03215004	American Gene Technologies International Inc.	N/A	February 2021

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DOLUVOIR: Cartography of virologic reservoir related to antiretroviral concentrations in HIV-1+ patients on first line treatment containing dolutegravir and associated nucleoside/nucleotide reverse transcriptase inhibitors backbone	NCT04133012	Inserm-ANRS	N/A	November 2020
Establish and characterize an acute HIV infection cohort in a high-risk population	NCT00796146	Southeast Asia Research Collaboration with Hawaii	N/A	July 2033 See supplemental references page
Evaluation of the role of HIV-1 Tat protein and anti-Tat immune response in HIV reservoir (ISS OBS T-005)	NCT04263207	Barbara Ensoli, MD, PhD, Istituto Superiore di Sanità	N/A	December 2023
FRESH (Females rising through education, support, and health)	Ragon Institute webpage (no clinicaltrials.gov entry)	Ragon Institute of MGH, MIT and Harvard	N/A	N/A See supplemental references page
FXReservoir: Study of the effects of farnesoid X receptor (FXR) ligands on the reactivation of latent provirus	NCT03618862	Hospices Civils de Lyon	N/A	January 2021
Genotyping FcγRs genes	NCT03130296	University Hospital, Strasbourg, France	N/A	February 2020
HEATHER: HIV reservoir targeting with early antiretroviral therapy	UK CPMS17589	University of Oxford/Medical Research Council/British HIV Association	N/A	September 2019 J Infect Dis. 2019 Nov 28; pii: jiz563
HIV-PRADA: HIV persistence in lymph node and peripheral blood	NCT03426189 (closed to enrollment)	University of Melbourne	N/A	January 2021
HIV-Mercuri: HIV study on measuring the reservoir on cellular level to cure infection	NCT04305665 (not yet open for enrollment)	University Hospital, Ghent	N/A	December 2025
Host & viral factors associated with HIV elite control	UK CPMS16146	University College London Hospitals NHS Foundation Trust	N/A	May 2021
HSCT-HIV: Allogeneic hematopoietic stem cell transplantation in HIV-1 infected patients	NCT02732457	Kirby Institute	N/A	September 2024
HUSH restriction in HIV+ patients	NCT04172480	Inserm-ANRS	N/A	September 2022
iCHIP: Effect of immune checkpoint inhibitors on HIV persistence	hivcure.com.au (no registry entry)	University of Melbourne	N/A	N/A CROI 2020, Abstract 334

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IciStem: Collaborative project to guide and investigate the potential for HIV cure in HIV+ patients requiring allogeneic stem cell transplantation for hematological disorders	IciStem website (no clinicaltrials.gov entry)	amfAR	N/A	N/A CROI 2020, Abstract 339 CROI 2020, Abstract 348LB Lancet HIV. 2020 Mar 9. HIV Persistence Workshop 2019, Abstract OP 4.5 (see abstract book) Nature. 2019 Apr;568(7751):244-248. CROI 2019, Poster abstract 394 Ann Intern Med. 2018 Nov 20;169(10):674-683.
Identification and quantification of HIV CNS latency biomarkers	NCT02989285	St Vincent's Hospital, Sydney	N/A	December 2020
Impact of ART adherence on HIV persistence and inflammation	NCT02797093 (closed to enrollment)	University of Colorado, Denver	N/A	October 2020
Long-term effects of ART in acute HIV infection	ChiCTR1800015006	Key Laboratory of AIDS Immunology of National Health and Family Planning Commission, Department of Laboratory Medicine, The First Affiliated Hospital, China Medical University	N/A	December 2020

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Table 2. Observational Studies (Cont.)

Trial	Trial Registry Identifier(s)	Manufacturer/ Sponsor(s)	Phase	Estimated End Date/Interim Results
Measurement for viral reservoir and immune function in HIV-1+ patients under antiretroviral therapy	NCT04068441	National Taiwan University Hospital	N/A	December 2021
PITCH: Prospective interruption of therapy towards a cure for HIV pilot study	NHS Health Research Authority approval (not entered into any online registry yet)	University of Oxford	N/A	N/A
Post analytic treatment interruption study	NCT02761200	South East Asia Research Collaboration with Hawaii	N/A	March 2021
PRIMO (ANRS CO6): Primary infection cohort	NCT03148964	Inserm-ANRS	N/A	December 2020 See supplemental references page
Quantitative measurement and correlates of the latent HIV reservoir in virally suppressed Ugandans	NCT02154035 (closed to enrollment)	NIAID	N/A	December 2020 CROI 2020, Abstract 385 HIV Persistence Workshop 2019, Abstract OP 7.4 (see abstract book) Clin Infect Dis. 2017 Oct 15;65(8):1308-1315.
RESERVIH32: Bioclinical evaluation of two biomarkers of aviremic HIV-1 in CD4 T cells of adults undergoing treatment	NCT03940521 (not yet open for enrollment)	Centre Hospitalier Universitaire de Nîmes	N/A	June 2021
Role of the IL-33/amphiregulin pathway as a potential therapeutic target in HIV infection	NCT03622177	Inserm-ANRS	N/A	September 2023
SCOPE-ATI: SCOPE analytic treatment interruption protocol	NCT04359186 (not yet open for enrollment)	UCSF	N/A	June 2024
TESOVIR: Tracking and exploring the source of viral rebound (ART interruption)	NCT03117985	Centre Hospitalier Régional d'Orléans	N/A	September 2022

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Table 2. Observational Studies (Cont.)

Trial	Trial Registry Identifier(s)	Manufacturer/ Sponsor(s)	Phase	Estimated End Date/Interim Results
The Last Gift Study (for people with HIV and less than 6 months life expectancy due to terminal illness)	UCSD study website	University of California, San Diego (UCSD)	N/A	N/A J Clin Invest. 2020 Jan 7 HIV Persistence Workshop 2019, Abstract PP 5.7.5 (see abstract book)
The use of leukapheresis to support HIV pathogenesis studies	NCT01161199	University of California, San Francisco	N/A	July 2020
Thinking and memory problems in people with HIV	NCT01875588	National Institute of Neurological Disorders and Stroke (NINDS)	N/A	February 2035
TRESAX: T follicular helper reservoir in axillary lymph nodes study	hivcure.com.au (no registry entry)	Kirby Institute	N/A	N/A

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Table 3. Completed Studies

Trial	Trial Registry Identifier(s)	Manufacturer/Sponsor(s)	Phase	Published/Presented Data
ADOPTIVE IMMUNOTHERAPY				
Early ART in combination with autologous HIV-specific cytotoxic T lymphocyte (CTL) infusion	NCT02231281	Yongtao Sun, MD, PhD, Tangdu Hospital, the Fourth Military Medical University	Phase III	N/A
Reconstitution of HIV-specific immunity against HIV	NCT02563509	Guangzhou 8th People's Hospital	Phase I/II	N/A
HIV-specific memory CD8 T cells adoptive immunotherapy	ChiCTR-ICR-15005775	Beijing You'an Hospital, Capital Medical University	Phase I	Front Immunol. 2019 Mar 18;10:437
HXTC: HIV 1 antigen expanded specific T cell therapy	NCT02208167	University of North Carolina, Chapel Hill	Phase I	Mol Ther. 2018 Oct 3;26(10):2496-2506.
ANTIBODIES				
CHERUB 001 Intravenous immunoglobulin in primary HIV infection	No clinicaltrials.gov entry	CHERUB (Collaborative HIV Eradication of viral Reservoirs: UK BRC)	N/A	HIV Med. 2017 Jul 18; doi: 10.1111/hiv.12524.
3BNC117 (broadly neutralizing monoclonal antibody)	NCT02446847	Rockefeller University	Phase II	Nature. 2016 Jul 28; 535(7613):556–560
3BNC117	NCT02588586	Rockefeller University	Phase II	N/A
UB-421 (antibody inhibitor of HIV binding to CD4 receptors)	NCT02369146	United BioPharma	Phase II	N Engl J Med. 2019 Apr 18;380(16):1535-1545
VRC01 (broadly neutralizing monoclonal antibody)	NCT02664415 (also entered in clinicaltrials.gov as NCT03036709)	National Institute of Allergy and Infectious Diseases (NIAID)	Phase II	IAS 2017, Abstract TUAB0106LB (slides , video)
10-1074 (broadly neutralizing monoclonal antibody)	NCT02511990	Rockefeller University	Phase I	Nat Med. 2017 Feb;23(2):185-191
3BNC117	NCT02018510	Rockefeller University	Phase I	Nature. 2015 Jun 25;522(7557):487-91

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Research Toward a Cure October 16, 2020

Table 3. Completed Studies (Cont.)

Trial	Trial Registry Identifier(s)	Manufacturer/Sponsor(s)	Phase	Published/Presented Data
ANTIBODIES (Cont.)				
3BNC117 + 10-1074	NCT02825797	Rockefeller University	Phase I	Nature. 2018 Sep;561(7724):479-484. Nat Med. 2018 Sep 26.
PGDM1400 +/- PGT121 +/- VRC07-523LS (broadly neutralizing antibodies)	NCT03205917	International AIDS Vaccine Initiative	Phase I	N/A
PGT121	NCT02960581	International AIDS Vaccine Initiative	Phase I	CROI 2019, Abstract 145, Webcast
vedolizumab	NCT02788175	NIAID	Phase I	AIDS 2018, WESS0102
VRC01	NCT02411539	NIAID	Phase I	N/A
VRC01	NCT02471326	NIAID	Phase I	N Engl J Med. 2016 Nov 24;375(21):2037-2050
VRC01	NCT02463227	NIAID	Phase I	N Engl J Med. 2016 Nov 24;375(21):2037-2050 CROI 2016, Abstract 32LB, Webcast
VRC01	NCT01950325	NIAID	Phase I	Sci Transl Med. 2015 Dec 23;7(319):319ra206
VRC01LS, VRC07-523LS (long-acting broadly neutralizing antibodies)	NCT02840474	NIAID	Phase I	IAS 2019, Abstract WEAA0305LB (video, at 45:36)
ANTI-FIBROTIC				
ACE inhibitors	NCT01535235	UCSF/amfAR	Phase IV	Pathogens and Immunity. 2017;2(3):310-34.

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Table 3. Completed Studies (Cont.)

Trial	Trial Registry Identifier(s)	Manufacturer/Sponsor(s)	Phase	Published/Presented Data
ANTI-FIBROTIC (Cont.)				
losartan	NCT01852942	University of Minnesota	Phase II	CROI 2020, Abstract 277
telmisartan	NCT01928927	AIDS Clinical Trials Group	Phase II	CROI 2019, Abstract 395 J Infect Dis. 2018 217(11):1770-1781
telmisartan	NCT02170246	Yale University	Phase I	CROI 2019, Abstract 300
ANTI-INFLAMMATORY				
High dose vitamin D supplementation	NCT03426592	University of Melbourne	Phase II	N/A
CC-11050 (phosphodiesterase-4 inhibitor)	NCT02652546	NIAID	Phase I	AIDS 2018, Poster abstract LBPEB021
ANTIRETROVIRAL THERAPY				
dolutegravir in reservoirs	NCT02924389	Emory University	Phase N/A	AIDS. 2018 Jul 12. [Epub ahead of print]
HIV reservoir dynamics after switching to dolutegravir in patients on a PI/r based regimen	NCT02513147	Hospital Universitari Vall d'Hebron Research Institute	Phase IV	N/A
raltegravir or efavirenz + tenofovir + emtricitabine	NCT00734344	University of Alabama at Birmingham	Phase IV	N/A
ABX464	NCT02735863	Abivax S.A.	Phase II	J. Virus Eradication 2019;5:10-22
ABX464	NCT02990325	Abivax S.A.	Phase I/II	CROI 2020, Abstract 335 HIV Persistence Workshop 2019, Abstract OP 8.3 (see abstract book) 16th European Meeting on HIV & Hepatitis Treatment Strategies & Antiviral Drug Resistance 2018, presentation

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Table 3. Completed Studies (Cont.)

Trial	Trial Registry Identifier(s)	Manufacturer/Sponsor(s)	Phase	Published/Presented Data
ANTIRETROVIRAL THERAPY IN HIV CONTROLLERS				
emtricitabine + rilpivirine + tenofovir	NCT01777997	AIDS Clinical Trials Group/NIAID	Phase IV	J Infect Dis. 2020 June 4:jiaa294 Clin Infect Dis. 2019 May 25. CROI 2019, Poster abstract 508 CROI 2018, Poster abstract 229
raltegravir + tenofovir + emtricitabine	NCT01025427	University of California, San Francisco	Phase IV	PLoS Pathog. 2013;9(10):e1003691
ASSEMBLY INHIBITORS				
BIT225	ACTRN12617000025336	Biotron Limited	Phase II	The Journal of Infectious Diseases. jiaa635 CROI 2020, Abstract 506 HIV DART 2018
BIT225	ACTRN12612000696897	Biotron Limited	Phase I	J Antimicrob Chemother. 2016 Mar;71(3):731-8
COMBINATIONS				
maraviroc, dolutegravir, dendritic cell vaccine, auranofin, nicotinamide	NCT02961829	Federal University of São Paulo	Not listed	AIDS 2020, Abstract OAXLB0105 HIV Persistence Workshop 2019, Abstract OP 8.6 (see abstract book) Int J Antimicrob Agents. 2019 Aug 5. pii: S0924-8579(19)30212-2. CROI 2019, Poster abstract 399 AIDS 2018, Abstract WEPDB0105 (slides , video)

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Table 3. Completed Studies (Cont.)

Trial	Trial Registry Identifier(s)	Manufacturer/Sponsor(s)	Phase	Published/Presented Data
COMBINATIONS (Cont.)				
Adoptive transfer of haploidentical natural killer cells and IL-2	NCT03346499	University of Minnesota - Clinical and Translational Science Institute	Phase II	N/A
ERAMUNE-01 (antiretroviral intensification +/- interleukin-7)	NCT01019551	ORVACS/Cytheris SA/Merck Sharp & Dohme Corp./Pfizer	Phase II	AIDS. 2016 Jan;30(2):221-30
ERAMUNE-02 (DNA/Ad5 vaccine, ART intensification)	NCT00976404	Vical/GenVec/CHERUB/NIH Vaccine Research Center/ORVACS	Phase II	Lancet HIV. 2015 Mar;2(3):e82-91 CROI 2014, Poster abstract 422
disulfiram + vorinostat	NCT03198559 (suspended due to neurotoxicity)	The Peter Doherty Institute for Infection and Immunity	Phase I/II	CROI 2019, Abstract 401
GTU-MultiHIV B-clade + MVA HIV-B +/- vedolizumab (DNA + viral vector vaccines +/- anti- $\alpha_4\beta_7$ integrin antibody)	NCT02972450	Inserm-ANRS	Phase I/II	Terminated due to the bankruptcy of FITBiotech, the provider of the GTU DNA vaccine
Vacc-4x + romidepsin	NCT02092116	Bionor Immuno AS/Celgene	Phase I/II	CROI 2019, Abstract 397 Lancet HIV 2016, July 7, 2016
Vacc-4x (peptide-based therapeutic vaccine) + lenalidomide	NCT01704781	Bionor Immuno AS	Phase I/II	IAS 2015 Towards an HIV Cure Symposium, Poster Abstract PE61
vorinostat + hydroxychloroquine + maraviroc (VHM)	NCT02475915 NCT02470351 (CNS substudy)	South East Asia Research Collaboration with Hawaii	Phase I/II	J Virus Erad. 2020 (6) 10004 AIDS 2016, Abstract TUAX0101LB
AGS-004 + vorinostat	NCT02707900	NIAID	Phase I	Sci Rep. 2020 Mar 20;10(1):5134. IAS 2019, Poster abstract MOPEB272
chemotherapy + maraviroc in people with non-Hodgkin lymphoma	NCT02486510	Fundacion para la Investigacion Biomedica del Hospital Universitario Ramon y Cajal	Phase I	Terminated due to futility criteria

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Table 3. Completed Studies (Cont.)

Trial	Trial Registry Identifier(s)	Manufacturer/Sponsor(s)	Phase	Published/Presented Data
COMBINATIONS (Cont.)				
DCV3 (dendritic cell-based vaccine pulsed with autologous inactivated HIV) + pegylated interferon	NCT02767193	Judit Pich Martínez, Fundació Clínic per la Recerca Biomèdica	Phase I	CROI 2020, Abstract 282 The Journal of Infectious Diseases, jjz611
MVA.HIVconsv + romidepsin	NCT02616874	IrsiCaixa	Phase I	CROI 2017, Abstract 119LB, Webcast
MVA-B (viral vector vaccine) +/- disulfiram	NCT01571466	Hospital Clinic of Barcelona/HIVACAT	Phase I	PLoS One. 2015 Nov 6;10(11):e0141456. J Antimicrob Chemother. 2015 Feb 26. pii: dkv046.
MVA.HIVconsv + romidepsin	NCT02616874	IrsiCaixa	Phase I	Front Immunol. 2020 May 6:11:823. CROI 2019, Abstract 438 CROI 2017, Abstract 119LB, Webcast
CYTOKINES				
N-803	NCT02191098	University of Minnesota - Clinical and Translational Science Institute	Phase I	CROI 2018, Poster abstract 356
GENE THERAPIES				
OZ1	NCT00074997	Janssen-Cilag Pty Ltd	Phase II	Nat Med. 2009 Mar; 15(3): 285–292.
Cal-1: Dual anti-HIV gene transfer construct	NCT01734850	Calimmune	Phase I/II	N/A
SB-728mR-T (autologous CD4 T cells genetically modified at the CCR5 gene) + cyclophosphamide	NCT02225665	Sangamo BioSciences	Phase I/II	N/A

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Table 3. Completed Studies (Cont.)

Trial	Trial Registry Identifier(s)	Manufacturer/Sponsor(s)	Phase	Published/Presented Data
GENE THERAPIES (Cont.)				
SB-728-T + cyclophosphamide	NCT01543152	Sangamo BioSciences	Phase I/II	CROI 2016, Poster abstract 358LB CROI 2015, Poster abstract 434 CROI 2014, Abstract 141 , Webcast
SB-728-T	NCT01252641	Sangamo BioSciences	Phase I/II	N/A
VRX496 (gene-modified autologous CD4 T cells)	NCT00295477	University of Pennsylvania	Phase I/II	Blood. 2013 Feb 28; 121(9): 1524–1533
C34-CXCR4 (autologous CD4 T cells gene-modified to express HIV-inhibiting C34 peptide)	NCT03020524	University of Pennsylvania	Phase I	N/A
HGT43	No clinicaltrials.gov entry	Enzo Biochem	Phase I	AIDS 2006, Abstract MOPDA06
MazF-T (redirected MazF-CD4 autologous T cells)	NCT01787994	Takara Bio/University of Pennsylvania	Phase I	CROI 2015, Poster abstract 402
Redirected high affinity Gag-specific T cells	NCT00991224	University of Pennsylvania/Adaptimmune	Phase I	Study closed due to safety concern, see: Mol Ther. 2015 Jul; 23(7): 1149–1159.
SB-728mR-T + cyclophosphamide	NCT02388594	University of Pennsylvania	Phase I	CROI 2019, Abstract 25 , Webcast
SB-728-T	NCT01044654	Sangamo BioSciences	Phase I	ICAAC 2014, Abstract H-643; 2013, Abstract H-1464c
SB-728-T	NCT00842634	Sangamo Biosciences/University of Pennsylvania	Phase I	N Engl J Med. 2014 Mar 6;370(10):901–10
GENE THERAPIES FOR HIV-POSITIVE PEOPLE WITH CANCERS				
Stem cells gene-modified with M87o vector encoding HIV-inhibiting C46 peptide	NCT00858793	Universitätsklinikum Hamburg-Eppendorf	Phase I/II	N/A
Stem cells gene-modified to encode multiple anti-HIV RNAs (rHIV7-shI-TAR-CCR5RZ)	NCT00569985	City of Hope Medical Center	Phase I	Sci Transl Med. 2010 Jun 16; 2(36): 36ra43.

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Table 3. Completed Studies (Cont.)

Trial	Trial Registry Identifier(s)	Manufacturer/Sponsor(s)	Phase	Published/Presented Data
IMAGING STUDIES				
123I radiolabeled 3BNC117	NCT03468582	University of Lausanne Hospitals	Phase I	N/A
Radiolabeled 3BNC117 + Copper-64 radio isotope followed by MRI/PET scanning to detect HIV in vivo	NCT03063788	Bayside Health	Phase I	AIDS 2020, Abstract PEA0060
IMMUNE CHECKPOINT INHIBITORS				
cemiplimab (anti-PD-1 antibody)	NCT03787095	NIAID	Phase I/II	Pre-CROI Community HIV Cure Research Workshop 2020 (slides , video) ACTG announcement
BMS-936559 (anti-PD-L1 antibody)	NCT02028403	National Institute of Allergy and Infectious Diseases (NIAID)	Phase I	J Infect Dis. 2017 Jun 1;215(11):1725-1733 CROI 2016, Abstract 25 , Webcast
ipilimumab (anti-CTLA-4 antibody)	NCT03407105	Medarex	Phase I	PLoS One. 2018 Jun 7;13(6):e0198158
IRON CHELATORS				
deferiprone	NCT02456558	ApoPharma	Phase I	N/A
JANUS KINASE INHIBITORS				
ruxolitinib	NCT02475655	NIAID	Phase II	CROI 2019, Abstract 37 , Webcast
LATENCY-REVERSING AGENTS				
disulfiram (acetaldehyde dehydrogenase inhibitor)	NCT01286259	University of California, San Francisco/Johns Hopkins University/amfAR	Not specified	Clin Infect Dis. 2014 58 (6): 883-90
Chidamide	NCT02902185	Tang-Du Hospital	Phase II/III	N/A
vorinostat (HDAC inhibitor)	NCT01365065	Bayside Health/Merck	Phase II	PLoS Pathog. 2014;10(10):e1004473
valproic acid (HDAC inhibitor)	NCT00289952	McGill University/Canadian Foundation for AIDS Research/CIHR Canadian HIV Trials Network	Phase II	HIV Med. 2012 May;13(5):291-6
valproic acid	NCT00614458	University of North Carolina at Chapel Hill/NIAID/Abbott/Merck Sharp & Dohme	Phase II	PLoS One. 2010 5(2): e9390

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Table 3. Completed Studies (Cont.)

Trial	Trial Registry Identifier(s)	Manufacturer/Sponsor(s)	Phase	Published/Presented Data
LATENCY-REVERSING AGENTS (Cont.)				
Chidamide (HDAC inhibitor)	NCT02513901	Tang-Du Hospital	Phase I/II	AIDS 2018, Abstract WEAA0101 (slides , video)
disulfiram	NCT01944371	University of California, San Francisco/Monash University/amfAR	Phase I/II	CROI 2015, Poster abstract 428LB
panobinostat (HDAC inhibitor)	NCT01680094	University of Aarhus/Massachusetts General Hospital/Monash University/Karolinska Institutet/Novartis/amfAR	Phase I/II	CROI 2015, Abstract 109 , Webcast The Lancet HIV. 2014 Oct; 1(1): e13–e21
romidepsin (HDAC inhibitor)	NCT01933594	AIDS Clinical Trials Group/NIAID/Gilead	Phase I/II	CROI 2019, Abstract 26 , Webcast CROI 2018, Abstract 72 , Webcast
vorinostat	NCT01319383	University of North Carolina at Chapel Hill/NIAID/Merck.	Phase I/II	J Clin Invest. 2017 Aug 1;127(8):3126-3135. J Infect Dis. 2014 Sep 1;210(5):728-35 Nature. 2012 Jul 25;487(7408):482-5
bryostatin 1 (PKC agonist)	NCT02269605	Fundacion para la Investigacion Biomedica del Hospital Universitario Ramon y Cajal	Phase I	AIDS. 2016 Feb 17. [Epub ahead of print]
mTOR INHIBITORS				
Impact of Everolimus on HIV persistence post kidney or liver transplant	NCT02429869	UCSF	Phase IV	Am J Transplant. 2020 Aug 11
Sirolimus	NCT02440789	ACTG	Phase I/II	CROI 2019, Abstract 131 , Webcast
metformin	NCT02659306	McGill University Health Center	Phase I	CROI 2020, Poster abstract 229 CROI 2019, Poster abstract 301

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Trial	Trial Registry Identifier(s)	Manufacturer/Sponsor(s)	Phase	Published/Presented Data
OBSERVATIONAL STUDIES				
ACTG A5321: Decay of HIV-1 reservoirs in subjects on long-term antiretroviral therapy: The ACTG HIV reservoirs cohort (AHRC) study	N/A	AIDS Clinical Trials Group	N/A	9th HIV Persistence Workshop 2019, Abstracts OP 4.6, 5.6 & PP 4.4 (see abstract book) CROI 2018, Abstract 119 , Webcast Poster abstract 403LB PLoS Pathog. 2017 Apr; 13(4): e1006285
ANRS EP 44: Residual replication of HIV-1 in the gut associated lymphoid tissue (GALT)	NCT01038401	Inserm-ANRS	N/A	N/A
APACHE: Monitored antiretroviral pause in chronically infected HIV+ individuals with long-lasting suppressed viremia	NCT03198325	Ospedale San Raffaele	N/A	J Antimicrob Chemother. 2020 Jun 15:dkaa231. 9th HIV Persistence Workshop 2019, Abstract PP 5.7.10 (see abstract book) J Antimicrob Chemother. 2019 April 23. pii: dkz138
CHERUB 003 (prospective HIV chemotherapy cohort study)	NCT01902693	Imperial College London/CHERUB	N/A	N/A
Effects of dolutegravir based regimen on HIV-1 reservoir and immune activation	NCT02557997	University Hospital, Strasbourg, France	N/A	J Antimicrob Chemother. 2017 Dec 13.

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OBSERVATIONAL STUDIES (Cont.)				
EPIC4: Early Pediatric Initiation: Canada Child cure Cohort Study	CTN S 281	Canadian Institutes of Health Research (CIHR)/Canadian Foundation for AIDS Research (CANFAR)/International AIDS Society (IAS)	N/A	AIDS: December 02, 2019 Clin Infect Dis. 2019 Mar 28. pii: ciz251 2015 IAS Towards an HIV Cure Symposium, Abstract PE69LB AIDS 2014, Abstract TUAB0206LB (video) Clin Infect Dis. (2014) 59 (7): 1012-1019.
EURECA: Exploratory study of cellular reservoirs in blood	NCT02858414	Centre Hospitalier Universitaire de Besancon	N/A	Viruses. 2018 Apr 13;10(4).
HCURE: Analysis of the impact of HCV treatment by last generation direct antiviral agents (DAA) on antiviral Immunity and HIV DNA reservoir in coinfected HIV-HCV patients	NCT03244371	Assistance Publique Hopitaux De Marseille	N/A	N/A
HIV resistance and treatment strategies	NCT00581802	NIAID	N/A	N/A
HIV-STAR: HIV sequencing after treatment interruption to identify the clinically relevant anatomical reservoir	NCT02641756	University Hospital, Ghent	N/A	CROI 2020, Abstract 324 Cell Host Microbe. 2019 Sep 11;26(3):347-358.e7. AIDS 2018, Abstract WEAA0201 (slides, video) , poster abstract THPEB096
ImmunoCo27: Co-adaptation between HIV and CD8 cellular immunity	NCT02886416	Inserm-ANRS	N/A	N/A
IMPAACT 2015: Evaluation of the HIV-1 reservoir in the CNS of perinatally-infected youth and young adults with cognitive impairment	NCT03416790	IMPAACT	N/A	N/A
Impact of a short-term analytical treatment interruption and re-initiation of antiretroviral therapy on immunologic and virologic parameters in HIV+ individuals	NCT03225118	NIAID	N/A	J Infect Dis. 2020 May 22:jiaa270.
In vitro autologous vaccine development to activate HIV reservoirs	UK CPMS17532	Imperial College London/amfAR	N/A	N/A

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Trial	Trial Registry Identifier(s)	Manufacturer/Sponsor(s)	Phase	Published/Presented Data
OBSERVATIONAL STUDIES (Cont.)				
ISALA: Analytical treatment interruption in HIV positive patients	NCT02590354	Institute of Tropical Medicine, Belgium	N/A	J Int AIDS Soc. 2020 Feb;23(2):e25453. CROI 2019, Poster abstract 389, Webcast
LoViReT: Low viral reservoir treated patients	NCT02972931	IrsiCaixa	N/A	EBioMedicine. 2020 Jun 21;57:102830. CROI 2020, Abstract 374 HIV Persistence Workshop 2019, Abstract OP 3.5 (see abstract book) HIV Persistence Workshop 2017, Abstract OP 8.6
MUCOVIR: Exploration of HIV reservoirs	NCT01019044	Objectif Recherche Vaccins SIDA	N/A	JAIDS. 2013 Mar 1;62(3):255–9
PembroHIV: Treatment with immunological checkpoint inhibitors of HIV+ individuals with cancer	NCT03767465	IrsiCaixa	N/A	HIV Persistence Workshop 2019, Abstract PP 4.2 (see abstract book)
Role of anti-Tat immunity on disease progression in HIV+ asymptomatic adults	NCT01029548	National HIV/AIDS Research Center (CNAIDS), Istituto Superiore di Sanità, Rome, Italy	N/A	Retrovirology. 2014 Jun 24;11:49.
Role of anti-Tat immunity on disease progression in HIV+ cART-treated adults	NCT01024556	CNAIDS, Istituto Superiore di Sanità, Rome, Italy	N/A	N/A
Seroprevalence of anti-Tat antibodies in HIV+ South African patients	NCT01359800	CNAIDS, Istituto Superiore di Sanità, Rome, Italy	N/A	N/A
Size of the HIV-1 reservoir and ongoing replication in defined cohorts	UK CPMS16004	University College London/amfAR	N/A	N/A
Specimen repository for HIV immunopathogenesis	NCT03579381	AIDS Healthcare Foundation	N/A	N/A
Tissue drug levels of HIV medications	NCT01490346	University of Minnesota – Clinical and Translational Science Institute/NIAID	N/A	Proc Natl Acad Sci USA. 2014 Feb 11;111(6):2307–12.

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Table 3. Completed Studies (Cont.)

Trial	Trial Registry Identifier(s)	Manufacturer/Sponsor(s)	Phase	Published/Presented Data
OBSERVATIONAL STUDIES (Cont.)				
ULTRASTOP (Towards HIV Functional Cure) ERAMUNE-03 (antiretroviral treatment interruption)	NCT01876862	Objectif Recherche VACCin Sida (ORVACS)/Fondation Bettencourt Schueller	N/A	AIDS, Published Ahead-of-Print, January 4, 2016
VIRECT: Impact of pre-ART CD4 T cell level on the rectal reservoir in long-term HIV-1 treated men	NCT02526940	Centre Hospitalier Universitaire de Saint Etienne	N/A	N/A
STEM CELL TRANSPLANTATION				
BMT CTN 0903: Allogeneic transplant in individuals with chemotherapy-sensitive hematologic malignancies and coincident HIV infection	NCT01410344	National Heart, Lung, & Blood Institute/National Cancer Institute/Blood & Marrow Transplant Clinical Trials Network	Phase II	Biol Blood Marrow Transplant. 2019 Jul 4. pii: S1083-8791(19)30417-3. Journal of Clinical Oncology 35, no. 15 suppl (May 2017) 7006-7006.
Immune response after stem cell transplant in HIV-positive patients with hematologic cancer	NCT00968630	Fred Hutchinson Cancer Research Center	Phase II	N/A
Optimized antiretroviral therapy during allogeneic hematopoietic stem cell transplantation in HIV-1 individuals	NCT01836068	Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins	Phase I	Lancet HIV. 2020 Jul 7:S2352-3018(20)30073-4.
THERAPEUTIC VACCINES				
AGS-004 (personalized therapeutic vaccine utilizing patient-derived dendritic cells and HIV antigens)	NCT00672191	Argos Therapeutics	Phase IIb	J Acquir Immune Defic Syndr. 2016 May 1;72(1):31-8
AGS-004	NCT01069809	Argos Therapeutics	Phase IIb	AIDS Res Hum Retroviruses. 2018 Jan;34(1):111-122 IAS 2015 Towards an HIV Cure Symposium, Combination Therapy Trials Roundtable CROI 2014, Poster abstract 344
iHIVARNA-01 (TriMix & HIV antigen naked messenger RNA)	NCT02888756	Rob Gruters, Erasmus Medical Center	Phase IIa	Vaccines (Basel). 2019 Dec 6;7(4). pii: E209.
DermaVir (topically applied DNA vaccine)	NCT00711230	Genetic Immunity	Phase II	N/A

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Table 3. Completed Studies (Cont.)

Trial	Trial Registry Identifier(s)	Manufacturer/Sponsor(s)	Phase	Published/Presented Data
THERAPEUTIC VACCINES (Cont.)				
DermaVir	NCT00918840	Genetic Immunity	Phase II	N/A
GSK Biologicals HIV Vaccine 732462 (p24-RT-Nef-p17 fusion protein vaccine)	NCT01218113	GlaxoSmithKline	Phase II	Medicine (Baltimore). 2016 Feb;95(6):e2673
GTU-multiHIV + LIPO-5 (DNA + lipopeptide vaccines)	NCT01492985	Inserm-ANRS	Phase II	J Infect Dis. 2019 Jul 2;220(Supplement_1):S5-S6 AIDS. 2018 Oct 15 HIVR4P 2016, Abstract P27.09
Tat protein vaccine	NCT01513135 NCT02712489 (extended follow-up study)	CNAIDS, Istituto Superiore di Sanità, Rome, Italy	Phase II	Retrovirology. 2016 Jun 9;13(1):34
Tat protein vaccine	NCT00751595 NCT02118168 (extended follow-up study)	Barbara Ensoli, MD, Istituto Superiore di Sanità	Phase II	Front. Immunol. February 13, 2019 Retrovirology. 2015 Apr 29;12(1):33 PLoS One. 2010 Nov 11;5(11):e13540
Vacc-4x (peptide-based vaccine)	NCT01712256	Bionor Immuno AS	Phase II	PLoS One. 2019 Jan 30;14(1):e0210965.
Vacc-4x	NCT00659789	Bionor Immuno AS	Phase II	Lancet Infect Dis. 2014 Apr;14(4):291-300
VAC-3S (peptide-based vaccine)	NCT02041247	InnaVirVax	Phase II	NPJ Vaccines (2019) 4:1 IAS 2017, Abstract MOSY0404 (slides , video)
VAC-3S	NCT02390466	InnaVirVax	Phase I/IIa	N/A
VAC-3S (peptide-based vaccine)	NCT01549119	InnaVirVax	Phase I/IIa	IAS 2015 Towards an HIV Cure Symposium, Poster abstract PE67 LB 30 Years of HIV Science, 2013, Poster abstract 145

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Table 3. Completed Studies (Cont.)

Trial	Trial Registry Identifier(s)	Manufacturer/Sponsor(s)	Phase	Published/Presented Data
THERAPEUTIC VACCINES (Cont.)				
AGS-004	NCT02042248	University of North Carolina at Chapel Hill/Argos Therapeutics/U.S. National Institutes of Health (NIH)	Phase I/II	N/A
Autologous HIV-1 ApB DC Vaccine	NCT00510497	Sharon Riddler, University of Pittsburgh/NIAID	Phase I/II	J Infect Dis. 2016 May 1;213(9):1400-9
Dendritic cells pulsed with chemically inactivated HIV	NCT02766049	University of Sao Paulo General Hospital	Phase I/II	J. Cellular Immunotherapy xx (2016) 1-10 J Int AIDS Soc. 2014 Jan 10;17:18938
Dendritic cell vaccine	NCT00833781	Massachusetts General Hospital	Phase I/II	N/A
Dendritic cell vaccine (DCV-2)	NCT00402142	Hospital Clinic of Barcelona	Phase I/II	Sci Transl Med. 2013 Jan 2;5(166):166ra2
DermaVir	NCT00270205	AIDS Clinical Trials Group	Phase I/II	JAIDS. 2013 Dec 1;64(4):351-9
GTU®-MultiHIV B Clade Vaccine	NCT02457689	Imperial College London	Phase I/II	Front Immunol. 2019 Dec 13;10:2911.
Tat Oyi (protein-based vaccine)	NCT01793818	Biosantech	Phase I/II	Retrovirology. 2016 Apr 1;13:21
THV01 (lentiviral vector-based therapeutic vaccine)	NCT02054286	Theravectys S.A.	Phase I/II	N/A
TUTI-16 (synthetic HIV-1 Tat epitope vaccine)	NCT01335191	Thymon, LLC	Phase I/II	Hum Vaccin Immunother. 2012 Oct;8(10):1425-30
Vacc-C5 (peptide-based vaccine)	NCT01627678	Bionor Immuno AS	Phase I/II	JAIDS April 2018;77:57 BMC Infect Dis. 2017 Mar 24;17(1):228
Ad26.Mos.HIV + MVA-Mosaic	NCT02919306	Janssen Vaccines & Prevention B.V.	Phase I	Nat Med March 23, 2020. IAS 2019 HIV & HBV Cure Forum, FT5-1 Flash Talk

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Table 3. Completed Studies (Cont.)

Trial	Trial Registry Identifier(s)	Manufacturer/Sponsor(s)	Phase	Published/Presented Data
THERAPEUTIC VACCINES (Cont.)				
AFO-18 (peptide-based vaccine)	NCT01141205	Statens Serum Institut (SSI)/Ministry of the Interior and Health, Denmark/European and Developing Countries Clinical Trials Partnership (EDCTP)	Phase I	AIDS Res Hum Retroviruses. 2013 Nov;29(11):1504-12
AFO-18 (peptide-based vaccine)	NCT01009762	SSI/Rigshospitalet/Hvidovre University Hosp./Ministry of Interior & Health, Denmark	Phase I	Clin Immunol. 2013 Feb;146(2):120-30
AT20-KLH	MED-AT20-001	Medestea Research & Production SpA, Turin	Phase I	Vaccine. 2014 Feb 19;32(9):1072-8
ChAdV63.HIVcons + MVA.HIVcons (viral vector vaccines)	NCT01712425	IrsiCaixa/Fundació Lluita contra la SIDA/Hospital Clinic of Barcelona/HIVACAT/University of Oxford	Phase I	EClinicalMedicine. 2019 Jun 5;11:65-80. IAS 2015, Poster abstract MOPEA036
Dendritic cells loaded with HIV-1 lipopeptides	NCT00796770	Baylor Research Institute/ANRS	Phase I	PLoS Pathog. 2019 Sep 9;15(9):e1008011. Retrovirology 2012, 9(Suppl 2):P328
DermaVir	NCT00712530	Genetic Immunity	Phase I	PLoS One. 2012 7(5): e35416
D-GPE DNA + M-GPE MVA (DNA + viral vector vaccines)	NCT01881581	Centers for Disease Control and Prevention, China	Phase I	N/A
HIVAX (lentiviral vector-based therapeutic vaccine)	NCT01428596	GeneCure Biotechnologies	Phase I	Vaccine. 2020 May 6:S0264-410X(20)30485-0 Vaccine. 2016 Apr 27;34(19):2225-32
HIV-v (peptide-based vaccine)	NCT01071031	PepTcell Limited	Phase I	Vaccine. 2013 Nov 19;31(48):5680-6
iHIVARNA-01 (TriMix & HIV antigen naked messenger RNA)	NCT02413645	Biomedical Research Institute August Pi i Sunyer (IDIBAPS)	Phase I	AIDS. 2018 Oct 4. [Epub ahead of print]
JS7 DNA + MVA62B (DNA + viral vector vaccines)	NCT01378156	GeoVax, Inc.	Phase I	PLoS One. 2016 Oct 6:11(10):e0163164
MAG pDNA vaccine +/- IL-12	NCT01266616	NIAID	Phase I	N/A

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Trial	Trial Registry Identifier(s)	Manufacturer/Sponsor(s)	Phase	Published/Presented Data
THERAPEUTIC VACCINES (Cont.)				
MAG-pDNA + rVSV _{IN} HIV-1 Gag (DNA + viral vector vaccines)	NCT01859325	NIAID/Profectus Biosciences, Inc.	Phase I	J. Virology May 20, 2020 CROI 2019, Poster abstract 392, Webcast Sci Transl Med. 2017 Dec 6;9(419). pii: eaan8848
MVA.HIVconsv	NCT01024842	University of Oxford/Medical Research Council	Phase I	N/A
PENNVAX-B (Gag, Pol, Env) + electroporation	NCT01082692	Inovio Pharmaceuticals	Phase I	Retrovirology 2012, 9(Suppl 2):P276
PENNVAX-B +/- IL-12 or IL-15	NCT00775424	University of Pennsylvania	Phase I	N/A
Recombinant adenovirus type 5 vaccine	NCT02762045	Centers for Disease Control and Prevention, China	Phase I	N/A
rMVA-HIV + rFPV-HIV (viral vector vaccines) in young adults	NCT00107549	NIAID	Phase I	AIDS. 2011 Nov 28; 25(18): 2227–2234
Tat protein vaccine	NCT00505401 NCT01024595 (extended follow-up study)	CNAIDS, Istituto Superiore di Sanità, Rome, Italy	Phase I	Rev Recent Clin Trials. 2009 Sep;4(3):195-204 Vaccine. 2009 May 26;27(25-26):3306-12 AIDS. 2008 Oct 18;22(16):2207-9
TOLL-LIKE RECEPTOR AGONISTS				
MGN1703 toll-like receptor 9 (TLR-9) agonist	NCT02443935	University of Aarhus	Phase Ib/IIa	EBioMedicine. 2019 Jul 9. pii: S2352-3964(19)30440-2. AIDS. 2019 Mar 29 Clin Infect Dis. 2017 Mar 9
Poly-ICLC (TLR-3 agonist)	NCT02071095	Nina Bhardwaj, MD/Campbell Foundation/Oncovir, Inc.	Phase I/II	Front Immunol. 2019 Apr 9;10:725.

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TOLL-LIKE RECEPTOR AGONISTS (Cont.)				
vesatolimod (TLR-7 agonist) in ART-treated HIV controllers	NCT03060447	Gilead Sciences	Phase Ib	CROI 2020, Abstract 40 , Webcast
vesatolimod (formerly GS-9620) (TLR-7 agonist)	NCT02858401	Gilead Sciences	Phase Ib	Clinical Infectious Diseases , ciao1534 IAS 2019, Abstract WEAA0304 (slides)
TRADITIONAL CHINESE MEDICINE				
Triptolide wilfordii	NCT02219672	Peking Union Medical College	Phase III	N/A
TREATMENT INTENSIFICATION/EARLY TREATMENT				
enfuvirtide	NCT00051831	NIAID	Not listed	J Infect Dis. 2010 Jan 15;201(2):293–6
enfuvirtide	NCT00334022	Canadian Immunodeficiency Research Collaborative	Not listed	N/A
New Era Study: Treatment with multi-drug class (MDC) HAART	NCT00908544	MUC Research GmbH	Not listed	Front Immunol. 2018 Apr 30;9:811
PLUS: Pilot study on the effect of adding raltegravir +/- a second drug on HIV levels in the gut	NCT00884793	University of California, San Francisco	Not listed	J Infect Dis. 2010 Nov 15;202(10):1553–61 AIDS. 2010 Oct 23;24(16):2451–60
Anti-HIV medications for people recently infected with HIV	NCT00106171	NIAID	Phase IV	PLoS One. 2015 Oct 10(11):e0143259
DIORR: Dolutegravir impact on residual replication	NCT02500446	University of Melbourne	Phase IV	The Lancet HIV, Online First, April 8, 2018 CROI 2018, Abstract 71 , Webcast
DRONE: Impact of starting a dolutegravir-based regimen on HIV-1 proviral DNA reservoir of treatment naïve and experienced patients	NCT02370979	University Hospital, Strasbourg, France	Phase IV	N/A
LEOPARD: Latency and early neonatal provision of antiretroviral drugs clinical trial	NCT02431975	Columbia University	Phase IV	EClinicalMedicine 18 (2020) 100241

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TREATMENT INTENSIFICATION/EARLY TREATMENT (Cont.)				
ANRS 147 OPTIPRIM: Optimization of primary HIV-1 infection treatment	NCT01033760	Inserm-ANRS	Phase III	PLoS One. 2013; 8(5): e64219. PLoS One. 2013; 8(3): e59767 IAS 2013, Abstract WEAB0101 IAS Cure Symposium 2013, Presentation
maraviroc	NCT00808002	Germans Trias i Pujol Hospital	Phase III	AIDS. 2014 Jan 28;28(3):325-34
raltegravir + maraviroc	NCT00935480	Centre Hospitalier Intercommunal de Toulon La Seyne sur Mer	Phase III	N/A
raltegravir	NCT00554398	Germans Trias i Pujol Hospital	Phase III	Antivir Ther. 2012;17(2):355-64
VIRECURE: Impact of extremely early ART to reduce viral reservoir & induce functional cure of HIV infection	NCT02588820	David Garcia Cinca, Hospital Clinic of Barcelona	Phase III	N/A
Intense acute infection study	NCT01154673	University of Toronto	Phase II/III	N/A
maraviroc	NCT00795444	Fundación para la Investigación Biomédica del Hospital Universitario Ramón y Cajal/Pfizer	Phase II	AIDS. 2013 Aug 24; 27(13):2081-8. PLoS One. 2011; 6(12):e27864
peginterferon alfa-2a (Pegasys)	NCT00594880	Wistar Institute	Phase II	EBioMedicine. 2020 Aug 19;59:102945. J Infect Dis. 2013 Jan 15; 207(2): 213–222
peginterferon alfa-2b	NCT01935089	University of Pennsylvania/Wistar Institute	Phase II	CROI 2017, Poster abstract 326
peginterferon alfa-2b	NCT02227277	Wistar Institute	Phase II	HIV Persistence Workshop 2019, Abstract PP 4.1 (see abstract book) CROI 2019, Abstract 136, Webcast

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TREATMENT INTENSIFICATION/EARLY TREATMENT (Cont.)				
raltegravir	NCT00520897	Canadian Immunodeficiency Research Collaborative	Phase II	AIDS. 2012 Jan 14;26(2):167–74
raltegravir	NCT00807443	Fundación para la Investigación Biomédica del Hospital Universitario Ramón y Cajal	Phase II	AIDS. 2012 Sep 24;26(15):1885–94
Viral suppression after analytic treatment interruption in Thai patients who initiated HAART during acute HIV infection	NCT02614950	South East Asia Research Collaboration with Hawaii	Phase II	Nat Med. 2018 Jun 11 [Epub ahead of print] CROI 2017, Abstract 124, Webcast
alpha interferon intensification	NCT01295515	NIAID	Phase I/II	N/A
indinavir + zidovudine + lamivudine + nevirapine	NCT00001644	NIAID	Phase I	N/A

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