Dana-Farber Cancer Institute | Brigham Cancer Center

Select Trials in Hematologic Malignancies, Stem Cell Transplantation, and Cellular Therapies

Trial Name	Patient Population
Leukemia and Myelodysplastic Syndromes	
Acute myeloid leukemia *Newly diagnosed*	18-351/ NCT03709758: A phase 1b study of venetoclax in combination with intensive induction and consolidation chemotherapy in treatment-naïve patients with acute myelogenous leukemia **Principal Investigator**: Richard Stone, MD; 617-632-6028
Acute myeloid leukemia *Newly diagnosed*	17-623/ NCT03258931: A phase 3 randomized study of crenolanib versus midostaurin administered following induction chemotherapy and consolidation therapy in newly diagnosed patients with FLT3 mutated acute myeloid leukemia **Principal Investigator**: Richard Stone, MD; 617-632-6028
Acute myeloid leukemia *Relapsed/refractory*	19-467/ NCT04065399**:** A phase 1/2, open-label, dose-escalation and dose-expansion cohort study of SNDX-5613 in patients with relapsed/refractory leukemias, including those harboring an MLL/KMT2A gene rearrangement or nucleophosmin 1 (NPM1) mutation **Principal Investigator**: Richard Stone, MD; 617-632-6028
Acute myeloid leukemia *Relapsed/refractory*	19-606/ NCT04086264: A phase 1b/2 study of IMGN632 as monotherapy or combination with venetoclax and/or azacitidine for patients with CD123-positive acute myeloid leukemia **Principal Investigator**: Daniel DeAngelo, MD, PhD; 617-632-6028
Myelodysplastic syndromes *Newly diagnosed*	20-363/ NCT04313881: ENHANCE: A randomized, double-blind, multicenter study comparing magrolimab in combination with azacitidine versus azacitidine plus placebo in treatment-naïve patients with higher risk myelodysplastic syndrome **Principal Investigator**: Daniel DeAngelo, MD, PhD; 617-632-6028
Myelodysplastic syndromes *Relapsed/refractory*	17-718/ NCT02890329: A phase 1 study of ipilimumab in combination with decitabine in relapsed or refractory myelodysplastic syndrome/acute myeloid leukemia **Principal Investigator**: Jacqueline Garcia, MD; 617-632-6028
Lymphoma	
Mantle cell lymphoma *Newly diagnosed* *Relapsed/refractory*	21-040/ NCT04855695: A phase 1/2 study of acalabrutinib, venetoclax, and obinutuzumab (AVO) in patients with relapsed/refractory and previously untreated mantle cell lymphoma **Principal Investigator**: Austin Kim, MD; 617-582-8711
Diffuse large B-cell lymphoma *Relapsed/refractory*	20-069/ NCT04572763: A phase 1/2 study of copanlisib plus venetoclax for the treatment of relapsed/ refractory diffuse large B-cell lymphoma **Principal Investigator**: Jennifer Crombie, MD; 617-582-9086

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Non-Hodgkin lymphomas *Relapsed/refractory*	19-546/ NCT04082936: A phase 1 open-label, multicenter study evaluating the safety and pharmacokinetics of escalating doses of IGM-2323 in patients with relapsed/refractory non-Hodgkin lymphomas **Principal Investigator**: Philippe Armand, MD, PhD; 617-632-6246
Classic Hodgkin lymphoma *Relapsed/refractory*	21-204/ NCT04938232: A phase 2 multi-cohort trial of ipilimumab with and without nivolumab in patients with relapsed/refractory classic Hodgkin lymphoma **Principal Investigator**: Reid Merryman, MD; 617-632-6246
CLL	
Newly diagnosed	18-226/ NCT03580928: A phase 2 study of acalabrutinib, venetoclax, and obinutuzumab (AVO) for initial therapy of chronic lymphocytic leukemia **Principal Investigator**: Matthew Davids, MD, MMSc; 617-632-6331
Relapsed/refractory	18-089/ NCT03534323: A phase 1/2 study of duvelisib and venetoclax in patients with relapsed or refractory chronic lymphocytic leukemia or small lymphocytic lymphoma **Principal Investigator**: Matthew Davids, MD, MMSc; 617-632-6331
Richter's syndrome	16-596/ NCT03054896: CRC043: A phase 2 study of venetoclax in combination with dose-adjusted EPOCH-R for the therapy of patients with Richter's syndrome **Principal Investigator**: Matthew Davids, MD, MMSc; 617-632-6331
Multiple Myeloma, Plasma Cell Disorders	
High-risk smoldering multiple myeloma	20-408/ NCT04270409: A phase 3 randomized, open-label, multicenter study of isatuximab (SAR650984) in combination with lenalidomide and dexamethasone versus lenalidomide and dexamethasone in patients with high-risk smoldering multiple myeloma **Principal Investigator**: Irene Ghobrial, MD; 617-632-4198
Newly diagnosed *Relapsed/refractory*	19-389/ NCT03989414: A phase 1/2, multicenter, open-label, study to determine the recommended dose and regimen, and evaluate the safety and preliminary efficacy of CC-92480 in combination with standard treatments in patients with relapsed or refractory multiple myeloma or newly-diagnosed multiple myeloma **Principal Investigator**: Paul Richardson, MD; 617-632-2104
Relapsed/refractory	19-278/ NCT03215030: A phase 1/2a open-label study to investigate the safety and tolerability, efficacy, pharmacokinetics, and immunogenicity of TAK-573 as a single agent in patients with refractory multiple myeloma **Principal Investigator**: Omar Nadeem, MD; 617-632-4952
Relapsed/refractory	20-212/ NCT04126200: A phase 1/2 randomized, open-label platform study utilizing a master protocol to study belantamab mafodotin (GSK2857916) as monotherapy and in combination with anti-cancer treatments in patients with relapsed/refractory multiple myeloma – DREAMM5 **Principal Investigator**: Paul Richardson, MD; 617-632-2104

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AL amyloidosis *Stage IIIa*	20-585/ NCT04512235: A phase 3, double-blind, multicenter study to evaluate the efficacy and safety of CAEL-101 and plasma cell dyscrasia treatment versus placebo and plasma cell dyscrasia treatment in plasma cell dyscrasia treatment-naïve patients with Mayo stage IIIa AL amyloidosis **Principal Investigator**: Giada Bianchi, MD; 617-525-4953
AL amyloidosis *Stage IIIb*	20-586/ NCT04504825: A phase 3, double-blind, multicenter study to evaluate the efficacy and safety of CAEL-101 and plasma cell dyscrasia treatment versus placebo and plasma cell dyscrasia treatment in plasma cell dyscrasia treatment-naïve patients with Mayo stage IIIb AL amyloidosis **Principal Investigator**: Giada Bianchi, MD; 617-525-4953
Waldenström's Macroglobulinemia	
Newly diagnosed	19-651/ NCT04273139: A phase 2 study on the combination of ibrutinib and venetoclax in treatment naïve patients with Waldenström Macroglobulinemia **Principal Investigator**: Jorge Castillo, MD; 617-632-4218
Newly diagnosed	21-439/ NCT05065554: A phase 2 study on acalabrutinib and anti-CD20 antibody in patients with anti-MAG mediated neuropathy **Principal Investigator**: Jorge Castillo, MD; 617-632-4218
Newly diagnosed *Relapsed/refractory*	20-081/ NCT04274738: A phase 1b trial of mavorixafor, an oral CXCR4 antagonist, in combination with ibrutinib in patients with Waldenstrom's Macroglobulinemia (WM) whose tumors express mutations in MYD88 and CXCR4 **Principal Investigator**: Steven Treon, MD, PhD; 617-632-2681
Cellular Therapies	
CNS lymphoma *Relapsed/refractory*	20-274/ NCT04608487: A phase 1 study of anti-CD19 CAR T-cell therapy with axicabtagene ciloleucel (axi-cel) in patients with relapsed/refractory primary and secondary central nervous system (CNS) lymphoma **Principal Investigator**: Caron Jacobson, MD, MMSc
Multiple myeloma *Relapsed/refractory*	19-785/ NCT04318327: A phase 1 open-label study of B-cell maturation antigen (BCMA)-directed CAR-T cells (new manufacturing process) in adult patients with relapsed and/or refractory multiple myeloma **Principal Investigator**: Adam Sperling, MD, PhD; 617-632-4218
Acute lymphoblastic leukemia *Relapsed/refractory*	20-562/ NCT04150497: A phase 1 open-label, dose-escalation and dose-expansion study to evaluate the safety, expansion, persistence and clinical activity of UCART22 (allogeneic engineered T-cells expressing anti-CD22 Chimeric Antigen Receptor) in patients with relapsed or refractory CD22+ B-cell acute lymphoblastic leukemia **Principal Investigator**: Daniel DeAngelo, MD, PhD; 617-632-6028
Head and neck cancer *Recurrent metastatic squamous cell carcinoma*	19-505/ NCT04290546: A phase 1 trial of CTLA-4 inhibition in combination with memory-like Natural Killer (NK) cell immune cell therapy in advanced head and neck cancer **Principal Investigator**: Glenn Hanna, MD; 617-632-3090

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Prostate cancer *Metastatic, castration-resistant*	20-075/ NCT04249947: A phase 1 dose-escalation and expanded cohort study of P-PSMA-101 autologous CAR T cells in patients with metastatic castration-resistant prostate cancer **Principal Investigator**: Xiao Wei, MD, MAS; 617-632-4524
Cervical cancer *Recurrent, metastatic*	19-842/ NCT03108495: A phase 2, multicenter study to evaluate the efficacy and safety using autologous tumor infiltrating lymphocytes (LN-145) in patients with recurrent, metastatic or persistent cervical carcinoma **Principal Investigator**: Ursula Matulonis, MD; 617-632-5269
Stem Cell Transplantation	
Conditioning for allogeneic stem cell transplant for myeloid malignancies	18-283/ NCT03613532: A phase 1 study of venetoclax added to busulfan and fludarabine reduced intensity conditioning regimen for AML, MDS, and MDS/MPN overlap syndromes **Principal Investigator**: Jacqueline Garcia, MD; 617-632-1906
Relapse treatment	20-336/ NCT04678401: A pilot/phase 1 study of immunosuppression-free regulatory T-cell graft-engineered haploidentical hematopoietic cell transplantation in relapsed/refractory AML/MDS **Principal Investigator**: John Koreth, MBBS, DPhil; 617-632-3470
Relapse treatment	19-142/ NCT03912064: A phase 1 trial of CD25/Treg-depleted DLI plus ipilimumab for myeloid disease relapse after matched-HCT **Principal Investigator**: John Koreth, MBBS, DPhil; 617-632-3470
Relapse treatment	19-265/ NCT04024761: A phase 1 trial of CIML NK cell infusion for myeloid disease relapse after haploidentical hematopoietic cell transplantation **Principal Investigator**: Roman Shapiro, MD; 617-632-3470
Graft-versus-host disease prevention	16-256/ NCT02867384: A randomized phase 2 study of obinutuzumab for prevention of chronic graft-versus-host disease after allogeneic peripheral blood stem cell transplantation **Principal Investigator**: Corey Cutler, MD, MPH, FRCPC; 877-442-3324
Graft-versus-host disease prevention and treatment	18-700/ NCT03422627: A phase 1b/2 open-label study evaluating the safety, tolerability, pharmacokinetics, pharmacodynamics, and efficacy of AMG 592 in adult patients with steroid refractory chronic graft-versus-host disease **Principal Investigator**: John Koreth, MBBS, DPhil; 617-632-3470
Graft-versus-host disease treatment	18-647/ NCT03763318: A phase 1b/2 study to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and the clinical activity of EQ001 in patients with newly diagnosed acute graft-versus-host disease **Principal Investigator**: John Koreth, MBBS, DPhil; 617-632-3470

The above-listed trials are a sampling of our many open and accruing studies.
If you would like more information about a clinical trial, please contact the principal investigator.

For a broader listing of our treatment protocols, please visit *dana-farber.org/clinicaltrials*.

These trials are conducted through Dana-Farber/Harvard Cancer Center,
an NCI-designated Comprehensive Cancer Center.