Open Clinical Trials for Patients With Lymphoma, Leukemia, and Esophageal Cancer

Providing access to clinical trials for veteran and active-duty military patients can be a challenge, but many trials are now recruiting patients from those populations. Some trials explicitly recruit patients seeking care at the US Department of Veterans Affairs (VA), US Department of Defense (DoD) Military Health System, and Indian Health Service. The VA Office of Research and Development alone supported > 7260 research projects in 2022, and many more are sponsored by Walter Reed National Medical Center and other major defense and VA facilities. The clinical trials listed below are all open as of July 20, 2023; have at least 1 VA or DoD location recruiting patients; and are focused on treatments for lymphoma, leukemia, and esophageal cancer. For additional information and full inclusion/exclusion criteria, please consult clinicaltrials.gov.

Lymphoma

➔ Study of a Triple Combination Therapy, DTRM-555, in Patients With R/R CLL or R/R Non-Hodgkin's Lymphomas

Targeted drug therapies have greatly improved outcomes for patients with relapsed or refractory (R/R) chronic lymphocytic leukemia (CLL) and non-Hodgkin's lymphoma. However, single drug therapies have limitations, therefore, the current study is evaluating a novel oral combination of targeted drugs as a way of overcoming these limitations. This study will determine the efficacy of the triple combination therapy, DTRM-555, in patients with R/R CLL or R/R non-Hodgkin's lymphoma.

ID: NCT04305444
Sponsor: Zhejiang DTRM Biopharma
Locations: 8 locations, including Memphis VA Medical Center

➔ Randomized Phase IIB Trial of Oral Azacytidine Plus Romidepsin Versus Investigator's Choice in PTCL (PTCL)

Peripheral T-cell lymphoma (PTCL) is a rare and heterogeneous group of non-Hodgkin lymphoma (NHL) originating from mature (or post-thymic or 'peripheral') T-lymphocytes and NK cells. They are considered very aggressive and are often resistant to conventional chemotherapy.

This study employs a stratified randomization with equal allocation within strata of patients to receive oral 5-azacytidine (AZA) plus romidepsin (ROMI) versus prespecified investigator choice (ROMI, belinostat, pralatrexate or gemcitabine), for the treatment of relapsed or refractory (R/R) PTCL. The dose and schedule of AZA/ROMI has been determined from a phase I clinical trial of the combination. The primary objective of this study is to estimate the progression-free survival (PFS) among patients receiving the combination compared to single agent of choice.

ID: NCT04747236
Sponsor: Collaborator: University of Virginia; Celgene
Locations: 4 locations, including VA Long Beach Health Care System

➔ Connect® Lymphoma Disease Registry: A US-Based Prospective Observational Cohort Study

This Disease Registry is designed to capture the patient characteristics, practice patterns, and therapeutic strategies evaluated in community and academic centers when treating relapsed/refractory (R/R) diffuse large B-cell lymphoma (DLBCL), and R/R follicular lymphoma (FL). The data collected in this Registry will facilitate the evaluation of the current treatment landscape for non-Hodgkin lymphoma (NHL), including the clinical effectiveness, safety. No investigational product or drug will be administered as part of this study. Enrolled patients will receive treatment and evaluations for their disease according to the standard of care and routine clinical practice at each study site. All treatments that patients receive for their disease will be recorded, including any previous lymphoma treatments. Clinical outcomes will be documented as part of an objective clinical assessment. In addition, patient-reported health-related quality of life (HRQoL) outcomes data will be collected from patients using various validated instruments. Social support data will also be collected.

ID: NCT04982471
Sponsor: Celgene
Locations: 60 locations, including VA Central California Health Care System, Harry S. Truman Memorial Veterans' Hospital, and Brooke Army Medical Center

➔ Obinutuzumab With or Without Umbralisib, Lenalidomide, or Combination Chemotherapy in Treating Patients With Relapsed or Refractory Grade I-IIIa Follicular Lymphoma

This phase II trial studies how well obinutuzumab with or without umbralisib, lenalidomide, or combination

chemotherapy work in treating patients with grade I-IIIa follicular lymphoma that has come back (relapsed) or does not respond to treatment (refractory). Immunotherapy with obinutuzumab, may induce changes in the body's immune system and may interfere with the ability of tumor cells to grow and spread. Umbralisib may stop the growth of cancer cells by blocking some of the enzymes needed for cell growth. Biological therapies, such as lenalidomide, use substances made from living organisms that may stimulate or suppress the immune system in different ways and stop cancer cells from growing. Chemotherapy drugs, such as cyclophosphamide, doxorubicin, vincristine, prednisone, and bendamustine, work in different ways to stop the growth of cancer cells, either by killing the cells, by stopping them from dividing, or by stopping them from spreading. It is not yet known whether giving obinutuzumab with or without umbralisib, lenalidomide, or combination chemotherapy will work better in treating patients with grade I-IIIa follicular lymphoma.

ID: NCT03269669

Sponsor: National Cancer Institute (NCI)

Locations: 427 locations, including VA Palo Alto Health Care System

➔ Brentuximab Vedotin and Nivolumab With or Without Ipilimumab in Treating Patients With Relapsed or Refractory Hodgkin Lymphoma

This phase I/II trial studies the side effects and best dose of ipilimumab and nivolumab when given together with brentuximab vedotin, and how well they work in treating patients with Hodgkin lymphoma that has returned after a period of improvement (recurrent) or has not responded to previous treatment (refractory). Immunotherapy with monoclonal antibodies, such as ipilimumab and nivolumab, may help the body's immune system attack the cancer and may interfere with the ability of cancer cells to grow and spread. Brentuximab vedotin is a monoclonal antibody, brentuximab, linked to a toxic agent called vedotin. Brentuximab attaches to CD30-positive cancer cells in a targeted way and delivers vedotin to kill them. It is not known whether giving brentuximab vedotin and nivolumab with or without ipilimumab may kill more cancer cells.

ID: NCT01896999

Sponsor: National Cancer Institute (NCI)

Locations: 486 locations, including Walter Reed National Military Medical Center

Leukemia

➔ Testing Early Treatment for Patients With High-Risk Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Leukemia (SLL), EVOLVE CLL/SLL Study

This phase III trial compares early treatment with venetoclax and obinutuzumab versus delayed treatment with venetoclax and obinutuzumab in patients with newly diagnosed high-risk chronic lymphocytic leukemia or small lymphocytic lymphoma. Venetoclax is in a class of medications called B-cell lymphoma-2 (BCL-2) inhibitors. It may stop the growth of cancer cells by blocking BCL-2, a protein needed for cancer cell survival. Immunotherapy with monoclonal antibodies, such as obinutuzumab, may help the body's immune system attack the cancer, and may interfere with the ability of tumor cells to grow and spread. Starting treatment with the venetoclax and obinutuzumab early (before patients have symptoms) may have better outcomes for patients with chronic lymphocytic leukemia or small lymphocytic lymphoma compared to starting treatment with the venetoclax and obinutuzumab after patients show symptoms.

ID: NCT04269902

Sponsor: National Cancer Institute (NCI)

Locations: 545 locations, Tibor Rubin VA Medical Center, Minneapolis VA Medical Center, and Durham VA Medical Center

➔ Testing the Use of Steroids and Tyrosine Kinase Inhibitors With Blinatumomab or Chemotherapy for Newly Diagnosed BCR-ABL-Positive Acute Lymphoblastic Leukemia in Adults

This phase III trial compares the effect of usual treatment of chemotherapy and steroids and a tyrosine kinase inhibitor (TKI) to the same treatment plus blinatumomab. Blinatumomab is a Bi-specific T-cell Engager ('BiTE') that may interfere with the ability of cancer cells to grow and spread. The information gained from this study may help researchers determine if combination therapy with steroids, TKIs, and blinatumomab work better than the standard of care.

ID: NCT04530565

Sponsor: National Cancer Institute (NCI)

Locations: 180 locations, including Walter Reed National Military Medical Center

➔ Asciminib Monotherapy, With Dose Escalation, for 2nd and 1st Line Chronic Myelogenous Leukemia (ASC2ESCALATE)

This will be a multicenter Phase II open-label study of asciminib in CML-CP patients who have been previously treated with one prior ATP-binding site TKI with discontinuation due to treatment failure, warning or intolerance. (2L patient cohort). In addition, newly diagnosed CML-CP patients who may have received up to 4 weeks of prior

TKI are included in a separate 1L patient cohort.
ID: NCT05384587
Sponsor: Novartis
Locations: 26 locations, including VA Puget Sound Health Care System

➔ Connect® Myeloid Disease Registry

This Disease Registry will collect data on patient characteristics, treatment patterns and clinical outcomes. The objective is to describe how patients with myeloid diseases are treated; and to build a knowledge base regarding the effectiveness and safety of first-line and subsequent treatment regimens in both community and academic settings. Enrolled patients will receive treatment and evaluations for their disease according to the standard of care and routine clinical practice at each study site. All treatments that patients receive for their disease will be recorded, including initial treatment and any subsequent therapy. Data on treatment outcomes, including response rates as measured by the treating physician, evidence of progression, survival, and patient-reported outcomes will be collected quarterly on the electronic CRF.
ID: NCT01688011
Sponsor: Celgene
Locations: 240 locations, including VA Central California Health Care System, John D. Dingell VA Medical Center, Manchester VA Medical Center, Dallas VA Medical Center, White River Junction VA Medical Center, and VA Caribbean Healthcare System

Esophageal Cancer

➔ Non-endoscopic Esophageal Sampling to Detect Barrett's Esophagus and Esophageal Cancer in Veterans

This study seeks to incorporate non-endoscopic detection method (Esocheck/Esoguard) in primary care practice and test whether this screening modality increases the positive predictive value of upper endoscopy and increases the detection of Barrett's esophagus and esophageal cancer.

Currently, BE is diagnosed only when patients undergo endoscopy with esophagogastroduodenoscopy (EGD). However, due to the high cost of EGD and the lack of a randomized controlled trials supporting its efficacy, endoscopy to screen for BE is not routinely recommended. Current guidelines do recommend sedated EGD in patients with multiple BE risk factors, refractory GERD, or alarm symptoms. This strategy fails to detect BE in patients whose symptoms are well controlled with either over the counter medications or physician prescribed therapies. It also fails to detect BE in asymptomatic subjects who comprise 40% of those that develop EAC. Thus, < 10% of EACs are diagnosed as early stage lesions caught by surveillance of patients with previously detected BE. Ablative nonsurgical therapies that have been developed for preventing cancer in patients with BE with high-grade dysplasia over the past decade will have little impact and the 5-year survival for EACs will remain a dismal 18% unless more effective programs for identifying BE and early EAC are developed.

Esocheck/Esoguard is a FDA approved device designed to sample the distal esophagus and analyze the collected material for presence of two methylated DNA markers. The Specific Aims of this study are:

To determine sensitivity, specificity, positive and negative predictive value of Esocheck/Esoguard performed in routine practice for detecting BE in an at risk Veteran population

To compare the yield of detected BE using EGD alone vs. stepwise molecular diagnostics(Esocheck/Esoguard) and endoscopic screening strategy (EGD) in at risk Veteran population.
ID: NCT05210049
Sponsor: Cleveland VA Medical Research and Education Foundation
Location: Louis Stokes Cleveland VA Medical Center

➔ Progression of Gastroesophageal Reflux Disease and Barrett's Esophagus and the Creation of a Barrett's Registry

The purpose of this study is to determine or evaluate the risk factors such as smoking, family history etc. that cause esophageal cancer and to determine the genetic changes that lead to esophageal cancer. The investigators hypothesis is that systematic collection of data on the natural history of GERD and BE patients and risk factors for development of BE in patients with chronic GERD and progression of BE to dysplasia and adenocarcinoma will provide useful information to develop a decision model for risk stratification and risk reduction strategies in these patients.
ID: NCT00574327
Sponsor: Midwest Biomedical Research Foundation
Location: Kansas City VA Medical Center