MINIMAL RESIDUAL DISEASE TRIALS

Collected by Annie Delores, Feb 2022

RECENT TRIAL POSTINGS

Posted: Jan 27 2022
CORRECT Study of Minimal Residual Disease Detection in Colorectal Cancer (MRD)

The CORRECT - MRD II study will prospectively enroll patients who have undergone complete surgical resection for stage II or III colorectal cancer. Patients will be followed for a minimum of 3 years and up to 5 years for recurrence.

750 participants, Recruiting as of December 2021

4 states.

Exact Science

NCT05210283

https://clinicaltrials.gov/ct2/show/NCT05210283

Posted Feb

MRD Assay Evaluates Recurrence and Response Via a Tumor Informed Assessment (MARIA)

Brief Summary:

"This study recruits patient with solid tumor types for sample collection and monitoring. Participants will provide blood and archival tissue samples in order to create a Personalized Cancer Monitoring (PCM) assay. This assay will be used to detect circulating tumor DNA (ctDNA) levels in the blood over time and hopefully contribute to improvements in residual disease detection methods for future patients.

Results from this assay will be provided to participants and providers but providers are not asked to change patient care based on this information. "

Invitae Corporation 1000 patients

NCT05219734

https://clinicaltrials.gov/ct2/show/NCT05219734

RESOURCES

Can use this search to find new MRD trials:

"Minimal Residual Disease" Trial Search in the US

https://clinicaltrials.gov/ct2/results?term=Minimal+Residual+Disease&recrs=a&cond=colorectal+cancer&map_cntry=US

MAP Feature

https://clinicaltrials.gov/ct2/results/map/click?map.x=394&map.y=374&term=Minimal+Residual+Disease&recrs=a&cond=colorectal+cancer&mapw=1899

Can also put up to 16 NCT numbers to have a selected search.

SCREENING TRIALS

Gritstone Bio, Inc.

A Screening Study Targeting Tumor-specific Antigens

NCT05158621

100 patients, 7 states

Inclusion Criteria: known KRAS status

"Detailed Description:

The screening study can enroll multiple tumor types in multiple treatment settings for the potential inclusion in a treatment study. Patient's tumors are analyzed to determine if the patient's tumor contains sufficient mutations. This screening study is currently enrolling patients with localized colon cancer or metastatic colorectal cancer for the development of a patient-specific neoantigen-based cancer vaccine that requires a manufacturing period for each patient.

The process of generating a patient-specific neoantigen cancer vaccine involves multiple steps, including collection of patient tumor and blood specimens, performing next-generation sequencing (NGS), predicting the neoantigens to be included in the patient-specific vaccine, and the manufacture and release of the patient-specific vaccine.

Study participants will not receive any investigational treatment as part of this trial. Patients screened in this study may be able to enroll in a separate investigational treatment study sponsored by Gritstone, provided that the patient meets the specified eligibility criteria for that treatment study."

https://clinicaltrials.gov/ct2/show/NCT05158621?term=NCT05158621&draw=2&rank=1

Epidemiological Study to Determine the Prevalence of ctDNA Positivity in Participants With Stage II (High Risk) or Stage III CRC After Surgery With Curative (R0) Intent and Subsequent Adjuvant Chemotherapy With Monitoring of ctDNA During Clinical Follow-up

200 patients, observational trial (in CA, IL, WA)

More info from BioNTech Pharma Company website

"The Phase 2 trial is based on previous results from the Phase 1a/1b basket trial evaluating autogene cevumeran as a single agent and in combination with atezolizumab, an anti-PD-L1 antibody, in patients with solid tumors (NCT03289962). The data show the induction of neoantigen-specific T cell responses, a manageable safety profile and objective responses as indication of clinical activity.

In parallel to the ongoing Phase 2 study, BioNTech has initiated an epidemiological study (NCT04813627) to investigate ctDNA status in patients with stage II/III colorectal cancer following resection or prior to adjuvant chemotherapy to identify patients who might be potential candidates for the Phase 2 trial"

https://clinicaltrials.gov/ct2/show/NCT04813627

Solid Tumor Analysis for HLA Loss of Heterozygosity (LOH) and Leukapheresis for CAR T- Cell Manufacturing (BASECAMP-1)

Objective: "To collect information on how often a solid tumor cancer might lose the Human Leukocyte Antigen (HLA) by next generation sequencing and perform leukapheresis to collect and store an eligible participant's own T cells for future use to make CAR T-Cell therapy for their disease treatment."

https://clinicaltrials.gov/ct2/show/NCT04981119?term=NCT04981119&draw=2&rank=1

SITC21 abstract
https://jitc.bmj.com/content/9/Suppl_2/A522?fbclid=IwAR2JfnfNzJTO2HhYHV3OmRQsShvCLyXxKzp2_E30Iod6Hf_NJIsIUXKhxWY

INTERVENTIONAL (Chemotherapy)

A Phase II Randomized Therapeutic Optimization Trial for Subjects With Refractory Metastatic Cancers Using ctDNA: Rapid 1 Trial

University of Florida – 78 patients

Stage IV, MSS patients only No BRAF V600e mutations

"This randomized, phase 2 study will investigate the use of the Signatera ctDNA assay versus the standard scan-based approach to guide treatment in patients with metastatic colorectal cancer.

The aim of this study will be to measure and compare the overall survival, progression-free survival, and best overall response while on study of patients whose treatment has been guided by these two approaches."

Must have progressed or have demonstrated intolerance to first line therapy for metastatic disease. Individuals who recurred within 6 months of completion of oxaliplatin based adjuvant chemotherapy are also eligible.

They will be executing "pre-specified sequence of FDA-approved drugs and drug combinations”

https://clinicaltrials.gov/ct2/show/NCT04786600?draw=2

Diet/Supplements

DAILY: Vitamin D, Aspirin, ExercIse, Low Saturated Fat Foods StudY in Colorectal Cancer Patients with Minimal Residual Disease

(at MD Anderson - for Stage II, III, IV NED after surgery/ablation) but at risk for recurrence.

"Primary Objective:

To estimate the ctDNA clearance rate of colorectal cancer patients with minimal residual disease after 3 months of optimal lifestyle interventions

Secondary Objectives:

To evaluate the dynamics of ctDNA allele fractions after 3 months of optimal lifestyle To estimate the recurrence rate at 1 year in subjects who complete 3 months of optimal lifestyle interventions"

https://www.mdanderson.org/patients-family/diagnosis-treatment/clinical-trials/clinical-trials-index/clinical-trials-detail.ID2021-0320.html?fbclid=IwAR1iIgzHuH56YpXzzKHpOy-VGCjRspEagyU8WiLHyi0dFd1Gd4dTAMengJ8

CTDNA Observational trials

Minimal Residual Disease Assessment in Patients With Colorectal Cancer, the MiRDA-C Study

"This study investigates if circulating tumor DNA (ctDNA) and other tumor-related molecules/chemicals released in the blood can help doctors predict if colorectal cancer may come back or spread.

Tumors shed DNA and other cancer related chemicals into the blood that can be identified and studied further to provide information about the cancer. Information gathered from this study may help researchers better understand if ctDNA found in the blood can predict whether colorectal cancer may come back or spread."

1000 participants

Stage 1-4 Texas

NCT04739072

https://clinicaltrials.gov/ct2/show/NCT04739072

BESPOKE Study of ctDNA Guided Therapy in Colorectal Cancer –

trial recently expanded to ALL stages including Stage 4

Brief Summary:

"The BESPOKE CRC study will prospectively enroll patients who have undergone surgery for stage I to IV colorectal cancer (CRC) and who have residual formalin-fixed paraffin-embedded (FFPE) tissue available will provide FFPE and whole blood samples.

INTERVENTIONAL TRIALS (immunotherapy)

A Vaccine (Ad5.F35-hGCC-PADRE) for the Treatment of Gastrointestinal Adenocarcinoma

Thomas Jefferson University

"This phase IIA trial investigates the side effects of Ad5.F35-hGCC-PADRE vaccine and to see how well it works in treating patients with gastrointestinal adenocarcinoma. Ad5.F35-hGCC-PADRE vaccine may help to train the patient's own immune system to identify and kill tumor cells and prevent it from coming back."

https://jitc.bmj.com/content/8/2/e001046?utm_source=twitter&utm_medium=social&utm_term=hootsuite&utm_content=sme&utm_campaign=usage&fbclid=IwAR0Zbb53foTMV88VVrkRsufuQx2EBmkgv0Gp5kvU-dLWvTy5ekzSiVkLa2I

A PHASE IB STUDY OF IMMUNOTHERAPY WITH EX VIVO PRE-ACTIVATED AND EXPANDED CB-NK CELLS IN COMBINATION WITH CETUXIMAB, IN COLORECTAL CANCER PATIENTS WITH MINIMAL RESIDUAL DISEASE (MRD)

NCT05040568

"A study of immunotherapy with expanded CB-NK cells in combination with cetuximab, to evaluate activity against minimal residual disease in patients with colon cancer that have completed adjuvant treatment but are positive for ctDNA."

"This is a Phase Ib clinical trial to evaluate the safety and activity of expanded CB-NK cells in combination with cetuximab in patients with high-risk CRC who have completed adjuvant chemotherapy but are still positive for MRD (see Figure 5). A total of 15 patients with stage II-III, and resected stage IV CRC and positivity for MRD will be enrolled.

https://clinicaltrials.gov/ct2/show/NCT05040568?term=NCT05040568&draw=2&rank=1

A Study of ELI-002 in Subjects With KRAS Mutated Pancreatic Ductal Adenocarcinoma (PDAC) and Other Solid Tumor (AMPLIFY-201)

KRAS G12D, KRAS G12R, NRAS G12D, NRAS G12R

"The Phase 1A portion of the study is an open-label, dose-escalation, 3+3 design in which up to 18 subjects will be treated in 3 planned dose level cohorts. In this phase, increasing doses of Amph-CpG-7909 will be evaluated sequentially. Safety and pharmacodynamic data will be evaluated and a recommended Phase 2 dose (RP2D) will be determined in consideration of a maximum tolerated dose (MTD) if observed."

NCT04853017

https://clinicaltrials.gov/ct2/show/NCT04853017?term=NCT04853017&draw=2&rank=1

Pooled Mutant KRAS-Targeted Long Peptide Vaccine Combined With Nivolumab & Ipilimumab for Patients With Resected MMR-p Colorectal & Pancreatic Cancer

Phase 1 trial

30 patients, MSS KRAS

NCT04117087

https://clinicaltrials.gov/ct2/show/NCT04117087

TRIALS ALREADY ON THE CRCMRD website

A Phase II Clinical Trial Comparing the Efficacy of RO7198457 Versus Watchful Waiting in Patients With ctDNA-positive, Resected Stage II (High Risk) and Stage III Colorectal Cancer

This trial started recruiting for Stage II & III CRC patients on March 8, 2021.

Twenty-six locations in the US, Belgium, Germany and Spain
https://clinicaltrials.gov/ct2/show/NCT04486378

from Tom's trial finder at Fight CRC...the helpful links are published articles or conference abstracts that can be of use for due diligence.

Slides from #AACR20 (Steven Liu twitter account)
https://twitter.com/StephenVLiu/status/1275443693193854977?s=20&t=KwddnB8E5DmY_Mr415_YSw

IN THE NEWS:

Colorectal cancer researchers focus on minimal residual disease to guide treatment

November 2020

BY CLAYTON BOLDT, PH.D.

https://www.mdanderson.org/cancerwise/colorectal-cancer-researchers-focus-on-minimal-residual-disease-to-guide-treatment.h00-159386679.html?fbclid=IwAR0dso2bMbAneuOin3RuZneJoM6ChWiQ9rntBTMFZfKRHfBAYRkUjXfCqYg