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Lay Language Summary

MiRaDor

A proof-of-concept study of treatment efficacy by monitoring Minimal Residual Disease (MRD) using circulating tumor DNA (ctDNA) in hormone receptor-positive/HER2- negative (HR+/HER2-) early breast cancer (EBC)

Context

Breast cancer is the leading cancer in women and ranks second in cancer-related deaths in western countries. About 70-80% of newly diagnosed breast cancers are hormone receptor positive. Hormone receptor positive/HER2 negative (HR[+]/HER2[-]) breast cancer is characterized by breast tumors that are positive for estrogen receptors, progesterone receptors or both, and lack or have very low expression of the protein HER2. Currently, there is no test to know which patients will relapse on standard of care treatment. Therefore, there is a critical need for methods that are able to identify and predict recurrence risk as well as assess the effectiveness of treatments in a quicker manner.

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Recently, new methods of detection have been explored and developed. In particular, “liquid biopsy” methods based on the analysis of circulating tumor DNA (ctDNA) offer a non-invasive alternative to traditional biopsies. ctDNA, consisting of small tumor DNA fragments that are present in the bloodstream. As tumor cells go through their life cycle they can release fragments of their DNA into the blood, which can be detected in these liquid biopsies.

Minimal residual disease (MRD) is a term that describes the small number of tumor cells that remain in the blood during or after treatment. These cells are often undetectable by standard tests but capable of causing the disease to return. To have a MRD positive test means that there is residual or remaining disease still in the body. Recent studies have used ctDNA analysis to detect MRD and have found that it may serve to identify patients who are at risk of recurrence and those who might benefit from further treatment.

About MiRaDor and the patients

The MiRaDor trial is a proof-of-concept study which aims to test the usefulness of ctDNA-based MRD detection in HR[+]/HER2[-] early breast cancer patients who are at high-risk for a relapse. This trial is designed as a platform to evaluate how ctDNA changes over time and in response to treatment as an aid in determining patients who are likely to have disease recurrence. This could also help in analyzing the efficacy of escalating new therapies for patients who are experiencing a relapse.

The MiRaDor trial has two phases: ctDNA surveillance and treatment. The surveillance phase will include 1260 patients who have HR[+]/HER[-] early breast cancer and are currently on treatment with endocrine therapy. These patients will have their blood collected and ctDNA analyzed at different time points (every 3 months during the first year, and every 6 months afterwards) until their ctDNA result turns positive.

The small number of patients that will have a positive ctDNA result and who are without evidence of progression by imaging techniques will move to the treatment phase. In this phase, 40-60 patients will be put into in 1 of the 4 different treatment arms: (A) standard endocrine therapy (which will serve as control group); (B) giredestrant (a selective estrogen degrader); (C) giredestrant + abemaciclib (a cyclin-dependent kinase 4/6 inhibitor); or (D) giredestrant + inavolisib (for those patients who have a PIK3CA mutation). Treatment and assessments of ctDNA will continue until evidence of the disease getting worse, physician's and/or patient's decision, or until the end of study.

The primary objective is to evaluate the rate of patients with at least 90% decrease or clearance of ctDNA after 3 months of treatment. The study will also assess the amount of patients with 90% decrease in baseline ctDNA at 6, 9, and 12 months, patients with a 70% and 50% decrease in ctDNA at 3, 6, 9, and 12 months, and safety of the treatments and how well they are tolerated.

What do we expect from the study?

The MiRaDor clinical trial expects to early detect patient's progression and capture the decrease of baseline ctDNA of the different experimental arms, correlating ctDNA changes with efficacy of the different treatments.

MiRaDor is envisioned as a potential platform for enhanced patient monitoring, which will allow for early detection of signs that the breast cancer is getting worse so that physicians can provide timely therapeutic interventions to ultimately improve patient outcomes.

ABOUT MEDSIR

Founded in 2012, MEDSIR works closely with its partners to drive innovation in oncology research. Based in Spain and the United States, the company manages all aspects of clinical trials, from study design to publication, utilizing a global network of experts and integrated technology to streamline the process. The company offers proof-of-concept support and a strategic approach that helps research partners experience the best of both worlds from industry-based clinical research and investigator-driven trials. To promote independent cancer research worldwide, MEDSIR has a strategic alliance with Oncoclínicas, the leading oncology group in Brazil with the greatest research potential in South America.
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