



PHENOMENAL

Efficacy and safety of liposomal irinotecan in patients with HER2-negative breast cancer and brain metastases

IMPORTANT:

- The document contains the summary of a clinical trial, and its sole purpose is to communicate the results of it to the general public.
- This document is not intended to promote recruitment or provide medical advice.
- The results reflected in this document may contradict those of other trials.
- It is not recommended to make decisions based on the information collected in this document; it should always be consulted with a medical professional beforehand.

ABOUT THIS SUMMARY

SPONSOR: MEDICA SCIENTIA INNOVATION RESEARCH S.L.

CANCER TYPE: HER2-negative + brain metastases. Breast Cancer and brain metastases

PHASE: PHASE II

MEDICINE(S) STUDIED: liposomal irinotecan

DATES OF STUDY: Between July 2017 and April 2024

TITLE OF THIS STUDY: PHENOMENAL: Efficacy and safety of liposomal irinotecan in patients with HER2-negative breast cancer and brain metastases

PATIENTS NUMBER: 56

PHARMACEUTICAL PARTNER: Servier Affaires

DATE OF THIS REPORT: October 26th, 2024

CLINICAL TRIALS.GOV: [NCT03328884](https://clinicaltrials.gov/ct2/show/study/NCT03328884)

The content for this document was finalised by **Medica Scientia Innovation Research (MEDSIR) - Oncoclínicas&Co** on October 26th, 2024. The information in this summary does not include additional information available after this date.

What was the purpose of this study?

Cancer is a disease in which normal cells grow and divide uncontrollably. Sometimes, cancer cells leave the original tumor site and invade other areas of the body, where new tumors are formed in a process known as 'metastasis.' Breast cancer cells can spread to different organs (known as metastatic breast cancer, MBC), with the brain being one of the most common sites, known as brain metastases (BM). BM affect many cancer patients and increase the risk of death, especially in those with MBC.

There are different types of breast cancer based on the presence of molecules called "human epidermal growth factor receptor 2" (HER2) proteins on the breast cancer cell surface. HER2-negative breast cancer is the most common type of breast cancer and does not have HER2 proteins. HER2-positive is an aggressive breast cancer and is characterized by high levels of HER2. And HER2-low breast cancer has lower quantity of HER2. This is important to help doctors determine the best treatment option for each patient. HER2-negative MBC patients with central nervous system (CNS) involvement, which affects the brain and the spinal cord, have limited treatment options. Liposomal irinotecan (nal-IRI) is a novel formulation of irinotecan, a drug that blocks an enzyme called topoisomerase 1 preventing cancer cells from growing and multiplying. Moreover, irinotecan is encapsulated in liposomes, tiny fat bubbles that can carry drugs in a very effective way as it helps protect the drug and delivers it directly to the target cells, such as cancer cells, which in turn help reducing the side effects.

What did researchers want to find out?

PHENOMENAL study assessed the effectiveness of nal-IRI in HER2[-] MBC patients with CNS involvement by analyzing the percentage of patients who experienced a reduction in the size of their brain tumors (intracranial objective response rate) after receiving nal-IRI therapy. Other key measures included how well nal-IRI worked on tumors outside the brain (extracranial objective response rate), and its safety and tolerability, among others.

When and where did the studies take place?

Between July 2017 and April 2024, 56 pts were enrolled across 16 hospitals in Spain.

Countries

Spain

Who took part of this study?

- (a) Women or men ≥ 18 years;
- (b) HER2-negative MBC with CNS involvement;
- (c) ≥ 1 new BMs and/or stable or progressive BMs, following previous WBRT and/or SRS and/or surgery;
- (d) Pretreated with taxanes, if not formally contraindicated;
- (e) ≥ 1 prior chemotherapy for advance disease;
- (f) ECOG performance status ≤ 1 .

What were the results of the study?

Ten patients out of 51 (19.6%) with worsening BM achieved a clinically significant reduction in the size of their brain tumors and 1 out of 37 (2.7%) had a measurable shrinkage of tumors outside the brain. Interestingly, patients treated with nal-IRI showed a 1.5 month longer survival without the disease getting worse and a 6.4 month longer survival, regardless of whether the disease got better, stayed the same, or worsened.

What were the main medical conclusions?

PHENOMENAL study showed that nal-IRI had antitumor activity in HER2-negative MBC patients with progressive BMs. The overall survival results are clinically meaningful in this patient population with dismal prognosis. In addition, nal-IRI had a manageable toxicity profile and no new safety concerns were identified.

Where I can find more information?

Your doctor can help you understand more about this study and the results. Speak to your doctor about the treatment options available in your country. You should not make changes to your care based on the results of this or any single study. Keep taking your current treatment unless instructed by your doctor.

For more details, please visit:

<https://www.medsir.org/phenomenal-clinical-trial>

The full scientific report of this study is available online at:

<https://clinicaltrials.gov/>

Thank you who took part in the study

If you took part in this study, **Medica Scientia Innovation Research (MEDSIR) - Oncoclínicas&Co**, as the Sponsor, extends its gratitude for your participation. This overview will outline the findings of the study. If you have any queries regarding the study or its outcomes, please reach out to the doctor or staff at your study location.

Thank you who took part in the study

ABOUT Oncoclínicas & Co

Oncoclínicas&Co is the largest group dedicated to cancer treatment in Latin America, with a specialized and innovative model focused on the entire oncology care journey, combining operational efficiency, humanized care, and high specialization through a medical team composed of over 2,700 specialist physicians with an emphasis on oncology. With its mission to democratize cancer treatment, it offers a comprehensive system that integrates outpatient clinics with high-complexity cancer centers. The company operates 145 units across 39 Brazilian cities, allowing high-quality access in all regions it serves, aligned with world-class standards.

Focusing on technology, precision medicine, and genomics, Oncoclínicas performed approximately 635,000 treatments in 2023. It is the exclusive partner in Brazil of the Dana Farber Cancer Institute, affiliated with Harvard Medical School, one of the world's leading cancer research and treatments centers. The company also owns Boston Lighthouse Innovation, a bioinformatics firm based in Cambridge, United States, and holds shares in Medsir, a company dedicated to the development and management of clinical trials for independent cancer research, based in Barcelona, Spain. Recently, Oncoclínicas

expanded its operations to Saudi Arabia through a joint venture with the Al Faisaliah Group, bringing its mission to beat cancer to a new continent and providing advanced oncology care on a global scale by combining oncological hyperspecialization with innovative treatment approaches.

The company is part of the IDIVERSA index, launched by B3, highlighting companies committed to gender and racial diversity. For more information, visit: visit www.grupooncoclinicas.com

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. Learn how MEDSIR brings ideas to life: www.medsir.org