MEDSIR
MEDICA SCIENTIA INNOVATION RESEARCH

Lay Language Summary

EMPRESS

Preoperative Window Opportunity Study With Giredestrant or Tamoxifen in Premenopausal Women With ER+/HER2[-] & Ki67⩾10%

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:	ER+/HER2- Ki67⩾10% Early Breast Cancer
PHASE:	PHASE II
DATES OF STUDY:	2023-2024
TITLE OF THIS STUDY:	Preoperative Window Opportunity Study With Giredestrant or Tamoxifen in Premenopausal Women With ER+/HER2[-] & Ki67⩾10%
PATIENTS NUMBER:	92
PHARMACEUTICAL PARTNER:	Roche Pharma
MEDICINE(S) STUDIED:	Giredestrant and Tamoxifen
DATE OF THIS REPORT:	August 22nd, 2025
CLINICAL TRIALS.GOV:	NCT05659563

The content for this document was finalized by **Medica Scientia Innovation Research (MEDSIR)** on August 22nd, 2025. The information in this summary does not include additional information available after this date.

What is the purpose of this study?

Giredestrant is a potent, oral selective estrogen receptor degrader (SERD) and antagonist with antitumor activity in patients with ER+/HER2- breast cancer. In pre- and perimenopausal women, it is usually given with gonadotropin-releasing hormone (GnRH) analogs to suppress ovarian function. On the other hand, tamoxfen is the current standard of care endocrine therapy for premenopausal women with early ER+/HER2- breast cancer, but its antiproliferative effect may be limited.

The EMPRESS study is evaluating whether short-term preoperative treatment with giredestrant alone (without GnRH analogs) is more effective than tamoxifen in reducing tumor cell proliferation, as measured by Ki67, in premenopausal women with ER+/HER2- early breast cancer. The goal is to determine if giredestrant can provide superior antiproliferative activity and potentially improve outcomes in this patient population.

What do researchers want to find out?

First, researchers want to find if a new drug called giredestrant, given alone, can slow down the growth of breast cancer cells better than tamoxifen in young women who have not gone through menopause and have ER+/HER2- early breast cancer. They test this by checking how much the cancer cell growth marker, called Ki67, goes down after 15 days of treatment.

Then, they also want to find out how many women's cancers stop dividing almost completely, and whether giredestrant lowers the activity of certain hormones (such as estrogen and progesterone) that help the cancer grow. This will show if giredestrant could be a stronger option than tamoxifen before surgery.

When and where is the study going to take place?

The EMPRESS study took place between July 2023 and December 2024 in multiple hospitals across Spain and France. It was carried out as an international, multicenter clinical trial with patients enrolled from 20 different study sites.

Who is taking part of this study?

Eligible patients were untreated premenopausal women aged 18 years or older with an Eastern Cooperative Oncology Group (ECOG) performance status of 0–1. They had histologically confirmed ER[+]/HER2[-] BC, defined as cT1–T3, N0–1, Ki67 ⩾10% locally assessed. Patients with metastatic disease or bilateral, cT4, and/or cN2/3 tumors were excluded.

What were the results of the study?

The study showed that giredestrant worked better than tamoxifen at slowing down cancer cell growth. After 15 days of treatment, patients who received giredestrant had a larger drop in the tumor growth marker Ki67 compared with those who received tamoxifen.

More patients on giredestrant also reached “complete cell cycle arrest” (meaning the cancer cells almost stopped dividing), although this difference was not statistically significant. In addition, giredestrant strongly reduced the activity of estrogen and progesterone receptors, which are important drivers of this type of breast cancer.

Overall, the study met its main eindpoint: giredestrant, without hormone-suppressing injections, showed stronger anticancer activity than tamoxifen in premenopausal women with ER+/HER2- early breast cancer.

What are the main social implications?

The EMPRESS study is the first to suggest that giredestrant, a potent oral SERD, could be highly effective as hormone therapy in premenopausal women without the need for ovarian suppression, which is usually achieved with LHRH-a injections. These findings still need to be confirmed by ongoing studies of other oral SERDs and future prospective clinical trials. If validated, this approach could improve quality of life, treatment outcomes, and access to more effective therapies for young women with breast cancer.

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/clinical-trials/empress
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)**, 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.

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