MEDSIR
MEDICA SCIENTIA INNOVATION RESEARCH

Cancer Research

PALMIRA: Palbociclib rechallenge in hormone receptor-positive/HER2-negative advanced breast cancer

Why was this trial needed?

Combining CDK4/6 inhibitors with either letrozole or fulvestrant has become the most common first treatment for patients with HR+/HER2- advanced breast cancer, but once they progress, the optimal treatment is unclear.

It has been suggested that more adaptive mechanisms of resistance develop due to endocrine therapy than to CDK4/6 inhibition, therefore it is necessary to determine if continuing on the same CDK4/6 inhibitor could be beneficial to this patient population.

What was the design of the trial?

The study enrolled 198 patients with HR+/HER2- advanced breast cancer who had disease progression after initially responding to treatment of palbociclib and endocrine therapy. Patients were randomized to receive either endocrine therapy alone or palbociclib with endocrine therapy. The choice of endocrine therapy was switched based on the previously administered drug (patients previously treated with fulvestrant changed to letrozole, whereas patients previously treated with letrozole, anastrozole or exemestane were switched to fulvestrant).

What were the main results?

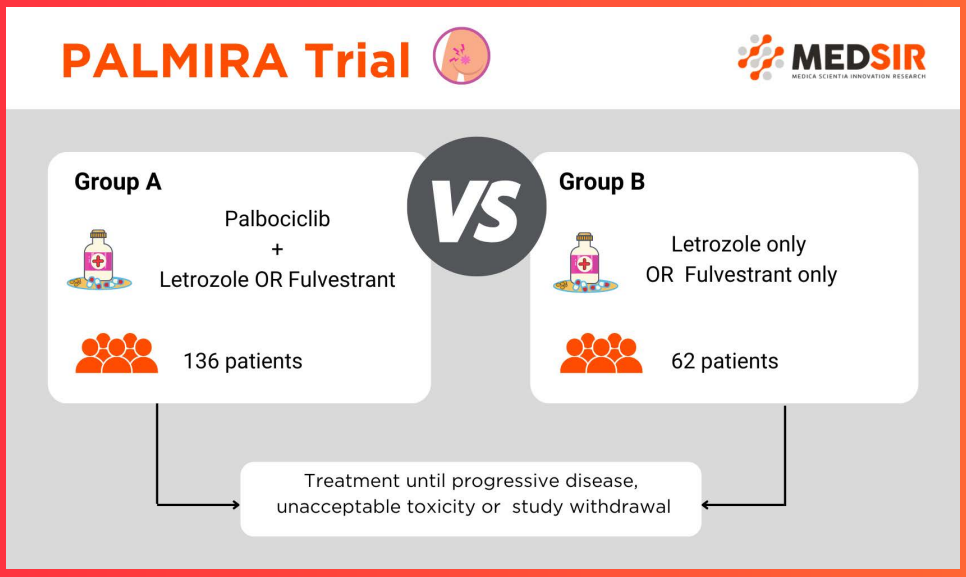
After a median follow up of 13.2 months, there was no significant difference in progression-free survival (PFS) between the two groups: the median PFS values were 4.9 months for the combination and 3.6 months for endocrine therapy alone. 6-month PFS rate was 42.1% for the combination and 29.1% for endocrine therapy alone.

Why is this trial important?

- Provided the answer that overall using palbociclib beyond progression does not improve PFS compared to standard endocrine therapy.
- Median PFS and clinical benefit rate at 6 months, as well as the activity in patients with aggressive disease suggest that there may be a subset of patients that benefit from palbociclib maintenance. Biomarker studies are planned to help identify this.

After a median follow up of 13.2 months, there was no significant difference in progression-free survival (PFS)

PALMIRA TRIAL



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