Cancer Council Victoria | Victorian Cancer Trials Link

A Phase 3, Randomized, Open-label Study to Evaluate the Efficacy and Safety of Sac-TMT (Sacituzumab Tirumotecan, MK-2870) Followed by Carboplatin/Paclitaxel vs Chemotherapy, Both in Combination With Pembrolizumab as Neoadjuvant Therapy for High-Risk, Early-Stage, Triple-Negative Breast Cancer or Hormone Receptor-low Positive/Human Epidermal Growth Factor Receptor-2 Negative Breast Cancer

Clinical summary

Researchers are looking for new ways to treat types of breast cancer that are both:

High-risk: the cancer may have a higher chance of getting worse or coming back after treatment
Early-stage: the cancer is in the breast or lymph nodes around the breast.

The two types of breast cancer in this study are triple-negative breast cancer (TNBC) and hormone receptor (HR)-low positive/human epidermal growth factor receptor-2 (HER2) negative breast cancer. These cancers have zero or a low amount of a protein called HER2 and other proteins that attach to the hormones oestrogen or progesterone.
Sacituzumab tirumotecan (also known as sac-TMT or MK-2870), the study medicine, is a type of targeted therapy. A targeted therapy is a treatment that works to control how specific types of cancer cells grow and spread.
The main goals of this study are to learn if people who receive sac-TMT, pembrolizumab immunotherapy, and chemotherapy:

Have fewer cancer cells found in the tumours and lymph nodes removed during surgery compared to those who receive only pembrolizumab and chemotherapy.
Live longer without the cancer growing, spreading, or coming back compared to people who receive only pembrolizumab with chemotherapy.

Eligible participants will be randomly allocated (by chance) to one of two treatment arms.
Experimental ArmParticipants will receive sac-TMT every 2 weeks plus pembrolizumab immunotherapy every 3 weeks for 12 weeks; and then they will receive pembrolizumab every 3 weeks and chemotherapy (carboplatin AUC + paclitaxel) weekly for 12 weeks.
3-6 weeks later, participants will have surgery and optional radiation therapy, and receive pembrolizumab either every 3 or 6 weeks for up to around 28 weeks. Additional treatment of the doctor's choice may be given to people with remaining disease.
Active Comparator ArmParticipants receive chemotherapy (carboplatin AUC and paclitaxel) weekly plus pembrolizumab every 3 weeks for 6 weeks; and then receive pembrolizumab every 3 weeks plus cyclophosphamide chemotherapy every 3 weeks and either doxorubicin or epirubicin for up to 12 weeks.
3-6 weeks later, participants will have surgery and optional radiation therapy, and receive pembrolizumab either every 3 or 6 weeks for up to around 28 weeks. Additional treatment of the doctor's choice may be given to people with remaining disease.

Conditions

This trial is treating patients with previously untreated, high-risk, early stage, non-metastatic triple negative or HR-low positive/HER2-negative

Trial Acronym
MK-2870-032

Trial Identifiers
NCT06966700
2870-032; U1111-1316-7898; JRCT2031250231
2024-520190-12-00

Cancer
Breast

Age: 18+
Phase: III

For full trial details, visit trials.cancervic.org.au/details/vctl_nct06966700