Cancer Council Victoria | Victorian Cancer Trials Link

A Phase 3, Randomized, Double-blind, Placebo-controlled Study Evaluating the Efficacy and Safety of Vepugratinib Combined With Enfortumab Vedotin and Pembrolizumab in Adults With Untreated Locally Advanced or Metastatic Urothelial Carcinoma With an FGFR3 Genetic Alteration

Clinical summary

You may be eligible if you have unresectable, locally advanced, or metastatic urothelial cancer, have a FGFR3 genetic alteration and have not had prior treatment for your advanced diesease. Prior treatment for an earlier stage disease is permitted.
The study includes a safety lead-in phase to evaluate the combination of vepugratinib, enfortumab vedotin, and pembrolizumab.
Once the safety and tolerability of this combination is confirmed, participants are then randomly assigned (by chance) to one of two treatment arms to receive either:

Vepugratinib, enfortumab vedotin, and pembrolizumab
Placebo, enfortumab vedotin, and pembrolizumab

Study participation could last up to approximately 6 years.

Conditions

This trial is treating patients with urothelial cancer that is locally advanced, metastatic or unable to be removed with surgery and has an FGFR3 gene mutation

Trial Acronym
FORAGER-2

Trial Identifiers
NCT07218380
27333; J4G-MC-JZVD
2025-522855-25-00

Cancer
Bladder, Urothelial

Age: 18+
Phase: III

For full trial details, visit trials.cancervic.org.au/details/vctl_nct07218380