

Predictors of Immune Related Adverse Events from the use of the Immunotherapy in Patients with Cancer

ACTRN12621001146886

Status RECRUITING
Sponsor Western Sydney University
Enrollment 120 participants

Plain Language Summary

Immunotherapy drugs called immune checkpoint inhibitors have transformed cancer treatment for many patients with solid tumours. However, they can sometimes cause the immune system to attack healthy tissues, leading to side effects that can range from mild rashes to serious inflammation of the lungs, gut, liver, or other organs. Predicting who will experience these side effects before treatment starts could allow doctors to monitor and manage them more proactively.

This study is building a database of cancer patients starting immune checkpoint inhibitor therapy and tracking them for side effects throughout treatment. Before and during the first few cycles, blood, stool, and tissue samples will be collected to look for biomarkers — measurable signals in the body — that might predict which patients are most at risk of immune-related side effects.

You may be eligible if you are 18 or older, have been diagnosed with a solid tumour cancer, and are about to start treatment with an immune checkpoint inhibitor (either alone or with chemotherapy). You are not eligible if you have already received immune checkpoint inhibitor treatment in the past.

Key Eligibility Criteria

Inclusion (6)

- All patients with histologically or cytologically confirmed solid organ malignancies starting immune checkpoint inhibitors alone or in combination with chemotherapy
- Patients receiving treatment in either the adjuvant or metastatic settings
- Age \geq 18 years
- Ability to provide informed consent for the study procedures and data collection
- Willingness and ability to comply with the study requirements
- ... and 1 more (see full listing online)

Exclusion (1)

- Patients with prior exposure to immune checkpoint inhibitors

Locations (2 total)

Liverpool Hospital - Liverpool, NSW, Australia
Campbelltown Hospital - Campbelltown, NSW, Australia

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12621001146886>

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