

Clinical Trials Program

Evaluating adoptive cell therapy to treat ovarian cancer using TILs conditioned with dendritic cells

July 1, 2015 to June 30, 2018 **Highlights** • World's first Phase I clinical trial to use adoptive cell therapy for ovarian \$592,000 from BioCanRx • World's first clinical test of a Canadian innovation new cases of ovarian to re-activate TILs derived cancer in 2015 from a patient's tumour. • First use of a TIL cancer therapy in Canada, imported by a world-\$888,000 renowned thought leader in tumour immunology. • Fosters the spread of this deaths from ovarian promising TIL platform cancer in 2015 to other clinical sites in TIL cells Canada. Tumour-inflitrating lymphocytes (TILs) conditioned using dendritic cells **About the project** Ovarian cancer is the fifth most deadly cancer in women and the most lethal gynecologic malignancy. Surgery and chemotherapy are currently the standard treatments, but the death rate for this cancer remains very high. This trial brings an innovative biotherapeutic approach that uses a population of cells from the immune system, called T cells, to treat this deadly disease.

T cells are white blood cells that have the ability to seek out and destroy tumours. The T cells found within a tumour are called tumour-infiltrating lymphocytes, or TILs. Known as adoptive cell therapy, this approach to cancer treatment takes a patient's own TILs and reactivates them in the laboratory before giving them back to the patient. This therapy has been tested in patients with metastatic melanoma and shows promise, serving as a catalyst to test it in ovarian cancer.

The team at UHN's Princess Margaret Cancer Centre has developed a novel method to increase the activity of TILs in the laboratory. As a result, this project will be a first-in-human clinical study on two fronts. It will evaluate this innovative method of activating TILs and will also be the first to use TIL therapy for ovarian cancer, specifically platinum-resistant ovarian cancer.

This study aims to serve as a basis for further clinical development of this "made in Canada" approach to TIL therapy and to determine its potential effectiveness as a therapy for what has traditionally been a very difficult cancer to treat.

A key component of this project will be training investigators, from across Canada, how to they can perform TIL therapy at their hospitals.



Clinical trial site and investigators

Trial sponsor

Princess Margaret Cancer Centre, University Health Network

Training

Sites to be determined

A critical component of this trial is to foster the spread of this promising approach to other clinical sites on Canada.

Princess Margaret Cancer Centre, University Health Network

Clinical investigators

Dr. Marcus Butler Dr. Amit Oza

Scientific investigators

Dr. Pamela Ohashi

Dr. Trevor Pugh

BioCanRx \$592,000 approved on June 10, 2015

Partner contributions

Princess Margaret Cancer Foundation

\$888,000 to fund support for production of clinical grade autologous and expanded tumour-infiltrating lymphocytes (TILs), patient treatment costs, and correlative assay costs.

July 1, 2015

Open first-in-human clinical trial

July 1, 2015 to June 30, 2016

• Enrol and treat patients 1 to 5

July 1, 2016 to June 30, 2017

- Enrol and treat patients 11 and 12
- Do clinical follow-up and monitoring studies
- Prepare manuscript

July 1, 2016 to June 30, 2017 • Enrol and treat patients 6 to 10

The power to kill cancer lies within us. Let's tell our bodies how.



