

Clinical Trial Fact Sheet

Phase Ib trial of pembrolizumab administered following adoptive cell therapy- A multiple cohort study; The ACTIVATE (Adoptive Cell Therapy InVigorated to Augment Tumor Eradication) Trial.

Key Information

Who may qualify?

- Patients who have metastatic melanoma with surgically unresectable stage III or stage IV, histologically confirmed, or,
- Patients who have platinum resistant ovarian cancer, histologically confirmed
- Patients who do not have a history of cardiac illness
- For full inclusion criteria, please click the link at the bottom of the page

Recruitment status

Active: recruiting

Key words

 TILs, activate, ACT, immune checkpoint inhibitor, pembrolizumab. melanoma. skin cancer, ovarian cancer, lymphocytes

Melanoma; Ovarian cancer

The goal of the study is to assess the feasibility and safety of a combination therapy approach using pembrolizumab treatment following lymphodepleting chemotherapy, tumor infiltrating lymphocytes.

rial sites

Princess
 Margaret Cancer
 Centre (Toronto)

About the project

The ACTIVATE clinical study will investigate the combination of adoptive cell transfer (ACT) and treatment with an immune checkpoint inhibitor in cancer patients for whom standard treatments have failed. ACT uses cancer-fighting immune cells grown in the laboratory to large numbers, then infused back to patients. Several Canadian groups, including the group led by Drs. Butler, Ohashi and Hirano at the Princess Margaret, are developing this strategy to bring better treatments to Canadians. This includes the use of tumor-infiltrating lymphocytes (TILs), immune cells that attack tumors. Long-lasting responses have been seen in some patients in clinical trials of TILs.

Immune checkpoint inhibitors (ICI) are a new class of anti-cancer drug. Immune checkpoints are the "brakes" of the immune system, and sometimes cancer cells use these checkpoints to prevent immune cells from attacking the cancer. ICIs block this process, allowing immune cells to eliminate cancer cells. However, for most cancers, tumor shrinkage occurs in only a minority of patients after treatment. As with ACT, improvements are needed to benefit more patients. It has been observed in the laboratory and in some patients that combining checkpoint inhibitors with ACT shows the potential for improved responses. Given these promising results, we are performing a clinical study of the combination of TILs and the ICI pembrolizumab. In this study, we are investigating the feasibility, safety and potential clinical benefit of this novel approach in cancer patients who are left with few therapeutic options.

For specific information to share with your doctor and care team <u>click here</u>

(URL--> https://bit.ly/20vY9U9 | Clinical Trial #: NCT03158935)