

The Selected Tumor-infiltrating Lymphocyte Against Refractory Melanoma-01 Trial (STAR-M01)

Key Information

Who may qualify?

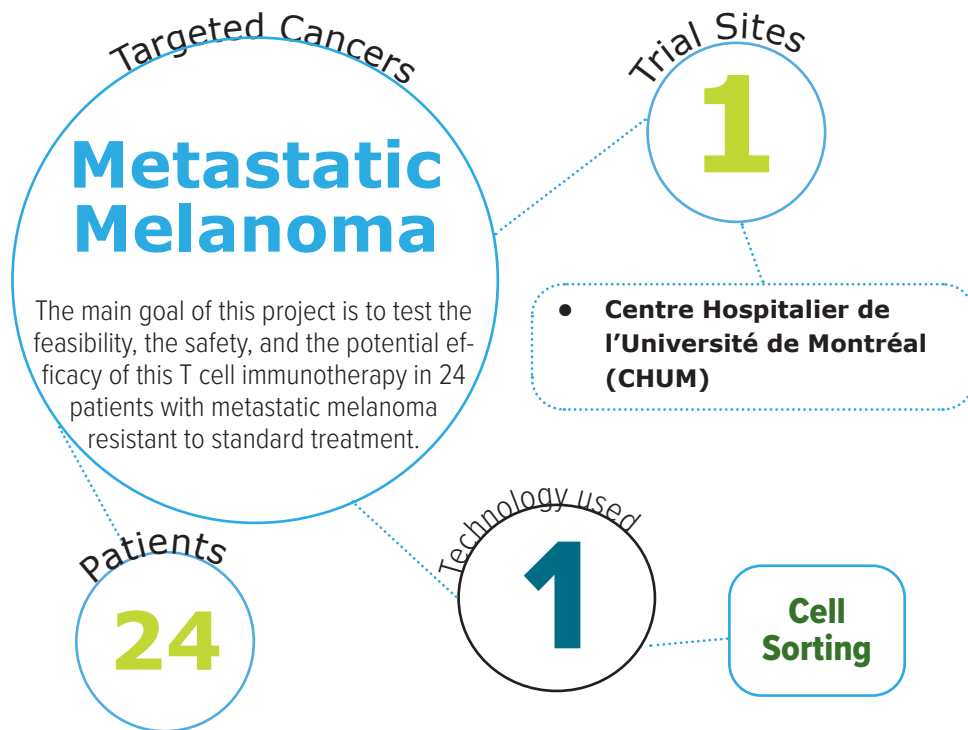
- Patients with advanced melanoma progressing on nivolumab or pembrolizumab (anti-PD-1) therapy. Patient with BRAF mutated tumor must also have progressed on vemurafenib (anti-BRAF) therapy
- Bearing a melanoma deposit (metastasis) that can be removed surgically for TIL production
- Good performance status, no major organ dysfunction, no immune dysfunction

Recruitment status

- Not yet recruiting

Key words

- Melanoma, T cell, transfusion, PD-1, cell sorting, tumour infiltrating lymphocytes (TILs)



About the Trial

A small number of anti-tumour immune cells, called T cells, can naturally infiltrate tumours in most patients, but they fail to control cancer growth. Current antibody-based immunotherapy designed to boost these anti-tumour T cells only works in a minority of patients.

Another way to therapeutically harness anti-tumor T cells consists of producing them in large numbers outside the body and transfusing them into patients. In this project, the researchers propose to make a T cell transfusion product highly enriched in tumor-reactive T cells using patients' own tumor as source material.

This is achieved by sorting T cells from a surgically removed tumor. Cell sorting is based on the expression by T cells of a cell surface marker called PD-1, which acts as a "tag" for tumor-reactivity. The researchers have optimized the parameters of a sophisticated cell sorter, and the cell culture conditions to expand the sorted T cells to large numbers for infusion into patients.

The main goal of this project is to test the feasibility, the safety, and the potential efficacy of this T cell immunotherapy in 24 patients with metastatic melanoma resistant to standard treatment. To guide the design of subsequent trials, this team will characterize the biologic features of the starting tumors and the T cell products for their association with treatment efficacy and side effects.

Enrolled patients will be able to participate in a patient-led support group to help them understand and communicate to others what to expect from anti-tumor T cell transfusion immunotherapy.

Clinical Trial #: TBD