BioCanRx
Canada's Immunotherapy Network
Le réseau canadien d'immunothérapie

Clinical Trials Program

Phase I study of therapy for acute myelogenous leukemia (AML) using autologous AML cells engineered to express IL-12

April 1, 2016 to March 31, 2021

Highlights

- This therapeutic approach has the potential to dramatically improve care for patients with relapsed AML through better outcomes and highly reduced toxicity risk, compared to current treatments.
- This approach overcomes many of the challenges associated with current treatment using matched donor bone marrow
- The systemic nature of this therapy can eradicate widespread disease.
- This approach can result in long-term immunological memory that is trained to recognize and attack cancer stem cells, by using a patient's own cancer cells as a vaccine platform.

Trial sites: 1

Patients: 12

Project value: $1.5 M
$373,980 from BioCanRx

Biotherapeutics: 1

AML Cells
Engineered AML cells with lentivirus expressing IL-12

Eligible cancers:
1,215 new cases of this cancer in 2010
Acute myelogenous leukemia (AML)
971 deaths from this cancer in 2011

$802,958
$10,000
$300,000

Krembil Foundation
Princess Margaret Hospital Foundation

cure: blood cancer

UHN

Partners: 3

About the project

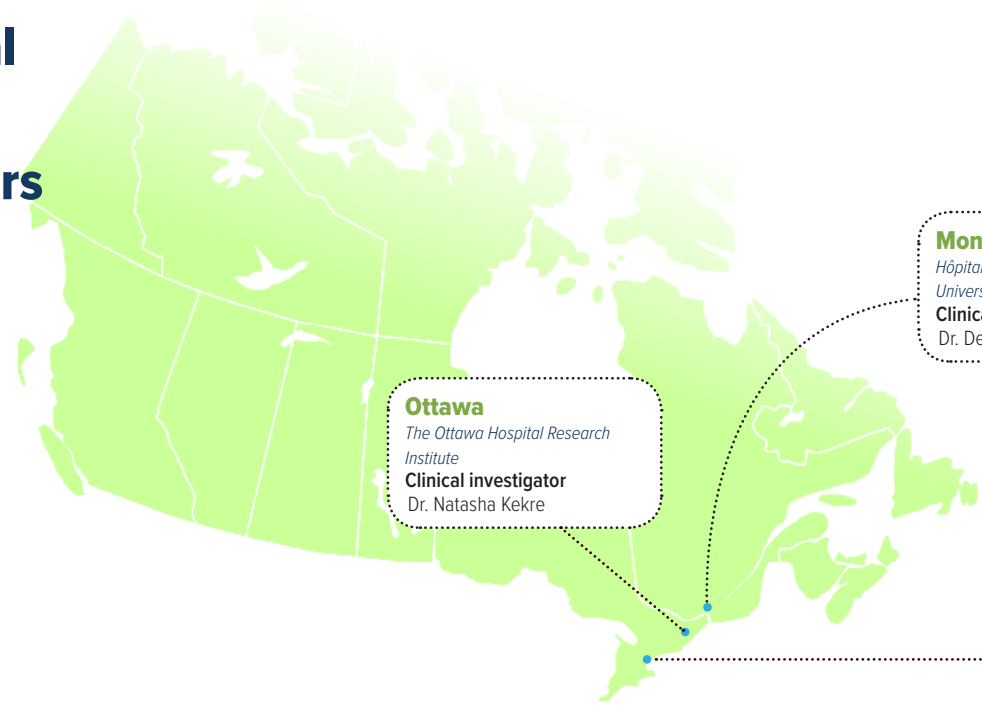
The immune system has the capacity to kill leukemia cells if properly instructed to do so. Some of the key instructions come in the form of soluble proteins that, if present in the right amounts, help immune system cells recognize leukemia cells and become activated to kill them.

The project team has previously shown that leukemia cells can be modified to secrete one of these proteins, called Interleukin 12, or IL-12. In experimental systems the leukemia cells secreting IL-12 stimulated a robust immune response that, once initiated, went on to kill all the residual leukemia cells even those not secreting IL-12. Acute myeloid leukemia (AML) is a life-threating disease for which, in many cases, there is no curative treatment. This project will test the safety of infusing 10 to 12 patients with some of their own AML cells that have been engineered to secrete IL-12.

The clinical trial will determine if an immune response has been initiated in both the patient's blood and bone marrow as treatment proceeds. It will also monitor the treatment's effect on the level of disease and follow each patient for two years.

Key investigator
Dr. Christopher Paige
Dr. Natasha Kekre
UHN Princess Margaret Cancer Centre
The Ottawa Hospital
L'Hôpital d'Ottawa

Clinical trial site and investigators



Trial sponsor
Princess Margaret Cancer Centre, University Health Network

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Hôpital Maisonneuve-Rosemont, Université de Montréal
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BioCanRx
$373,980
approved on Sept. 29, 2015

Partner contributions

Cure: Blood Cancer
$10,000

UHN
$300,000

Princess Margaret Cancer Centre Foundation & Krembil Foundation
$802,958

April 1, 2016
- Trial opens

- Protocol development, REB and Health Canada approvals
- Patient screening

- Enrol and treat patients 1 and 2 at dose level 1

- Enrol and treat patients 3 and 4 at dose level 2
- Complete analysis of of patients 1 and 2

- Enrol and treat patients 5 and 6 at dose level 3
- Complete analysis of patients 3 and 4

- Enrol and treat patients 7 and 8 at dose level 4
- Complete analysis of patients 5 and 6

- Enrol and treat patients 9 and 10 at dose level 5
- Complete analysis of patients 7 and 8

- Enrol and treat patients 11 and 12 at dose level 6
- Complete analysis of patients 9 and 10

- Complete follow-up and evaluation of:
  - primary safety objectives
  - secondary endpoint of response to treatment

BioCanRx
Biotherapeutics for Cancer Treatment
Biothérapies pour le traitement du cancer