

FAQ: Mesenchymal Stem cell therapy for Canadian MS patients (MESCAMS)

Revised January 2017

What are mesenchymal stem cells?

[Mesenchymal stem cells](#) (MSC) – found in many places in the body including the bone marrow, skin and fat – have been demonstrated to suppress inflammation and repair nerve tissue, positioning them as promising candidates for the treatment of multiple sclerosis (MS).

What is the MESCAMS study?

MESCAMS is the Canadian arm of an international study investigating the safety and efficacy of MSC therapy for MS. MESCAMS is a phase II, randomized, double-blind, placebo-controlled cross-over study that will take place at two Canadian sites – [The Ottawa Hospital](#) and [Health Sciences Centre \(HSC\) Winnipeg](#). MESCAMS is led by Dr. [Mark S. Freedman](#) (Ottawa Hospital Research Institute, University of Ottawa), who is also the Principal Investigator (PI) at the Ottawa site and Dr. [James J. Marriott](#) (University of Manitoba) who is the PI at the Manitoba site.

Study participants will receive either an early intravenous treatment of their own MSC extracted from their bone marrow, or a mock solution. At 24 weeks the reverse will occur, meaning that those who received the MSC initially will get the mock solution and those who started with the mock solution will get their MSC. Treatment safety and ability to reduce inflammation as measured by MRI will be observed at 24 weeks, and all participants will be followed for a total of 48 weeks.

When will MESCAMS begin?

The Ottawa site has received ethics approval, and is screening potential participants for recruitment. The research ethics board at the Winnipeg site has reviewed the proposal and approvals are in the process of being finalized. Please contact the appropriate personnel below for updates on recruitment and details about eligibility at either site.

What will the treatment entail?

All participants will have 20 ml of bone marrow extracted from the hip bone under local anesthesia. MSC will then be isolated from the bone marrow and multiplied over a period of approximately three weeks at highly specialized laboratories in Ottawa and Winnipeg, then frozen down. Participants will be randomly assigned to receive a single infusion of either their own MSC or a mock solution at week zero. At 24 weeks, participants will cross over to the opposite treatment arm (i.e., at the end of week 24, those who initially received their MSC will receive the mock solution and vice versa).

What are the risks of the treatment?

All potential and unknown risks and complications associated with the treatment will be explained to each participant before they make a decision about participating in the study. Only minimal risks have been identified by the principal investigators as being associated with this treatment. Common complications that may occur from the removal of bone marrow include pain during and after the procedure as well as bleeding and infection at the puncture site (where the needle goes in). With the IV infusion of MSC or placebo, individuals may experience fever, chills and rigors.

In order to freeze down and preserve the integrity of the MSC, a chemical called dimethylsulfoxide (DMSO) is used. DMSO is commonly used in the field of blood and marrow stem cell transplantation as a preservative. When individuals undergo the MSC or mock infusion they will receive a small amount of

DMSO. The most common side effects associated with DMSO administration include a mild drop or rise in heart rate and headache. Other rare side effects associated with DMSO administration may occur and will be explained in detail to each potential participant prior to providing informed consent.

How is MESCAMS different from the previously conducted stem cell trial in Canada?

This will be the first Canadian study evaluating the safety and benefit of mesenchymal stem cell therapy for multiple sclerosis. Unlike [previous studies](#) involving transplantation of [hematopoietic stem cells](#), chemotherapy (which often has serious side effects) will not be required.

Who will be eligible to participate in MESCAMS?

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- Male and female adults aged 18-50 diagnosed with multiple sclerosis:
 - Relapsing-remitting MS
 - Who have not responded to at least 1 year of therapy with one or more of the approved disease modifying therapies as evidenced by at least **one** of the following:
 - One or more clinically documented relapse in the past 12 months
 - Two or more clinically documented relapses in past 24 months
 - One or more gadolinium-enhancing lesion as seen on MRI within the past 12 months
 - Secondary-progressive MS:
 - Who have not responded to at least 1 year of therapy with one or more of the approved disease modifying therapies with **all** of the following:
 - an increase of one or more EDSS point in the past 12 months
 - one or more clinically documented relapse or one or more gadolinium-enhancing lesion as seen on MRI within the past 12 months
 - Primary progressive MS with **all** of the following:
 - an increase of one or more EDSS point in the past 12 months
 - one or more gadolinium-enhancing lesion as seen on MRI within the past 12 months
 - positive cerebrospinal fluid (CSF)
- Diagnosed with multiple sclerosis for **2-15** years.
- EDSS score of **2.5 to 6.5**.

This is not the complete list of inclusion criteria. For full inclusion and exclusion information please visit ClinicalTrials.gov

Who do I contact if I want to be considered as a participant in MESCAMS?

Individuals interested in participating in the MESCAMS study should consult with their neurologist. Their neurologist can then contact the following individuals:

The Ottawa Hospital:
Catherine Hilliker, RN
Phone: 613-737-8104 ext 7
Email: MESCAMS@ohri.ca

Health Sciences Centre (HSC) Winnipeg:
Angela Wilson, RN
Phone: 204-787-2905
Email: Stemcells_MS@hsc.mb.ca

How many participants will be accepted at each site?

Internationally, 160 participants will be enrolled in various clinical trials across nine countries. The Canadian component of the trial will enroll a total of 40 participants, 20 per study site.

Will MESCAMS only take place at the two sites, Ottawa and Winnipeg?

Yes. These two research facilities have been specifically constructed to harvest and manufacture stem cells and have been approved by the government to perform the procedure as outlined in the study protocol. In Canada, research sites must meet all government safety and design protocols as well as research ethics board criteria before moving forward with a clinical trial.

Can people from out of province participate in either of the trials?

The Ottawa site will be accepting participants from out of province; however participants will be required to cover the cost of travel and relocating to Ottawa for the entire duration of the trial as the study visits are frequent and the required assessments at each of these visits are quite intensive. The Winnipeg site is accepting participants from within Manitoba only. MS Society of Canada funding programs do not extend to coverage for travel or accommodation for participants of clinical trials.

If a person is not selected for this trial, are there other similar trials in North America or abroad that they could apply to participate in?

The protocol for the international study, including the associated Canadian trial, has been approved. The safety and ethics protocols in other mesenchymal stem cell trials unassociated with the MESCAMS trial are unknown and individuals should speak to their health care team if they are interested in learning more about mesenchymal stem cell treatment outside of Canada.

If MESCAMS is successful in demonstrating that MSC are safe and show benefit in treating MS, will it become an accepted treatment option?

Not quite. The goal of this phase II study will be to establish the safety of MSC in multiple sclerosis and investigate their ability to reduce inflammation and encourage repair. The hope is that the results from this study will provide evidence of repair and pave the way towards a larger phase III trial.