

Frequently Asked Questions: Lipoic Acid

#### June 2019

### 1. What is the Lipoic Acid Clinical Trial?

The MS Society of Canada is partnering with the National MS Society (U.S.) to fund a clinical trial to determine if the oral supplement, Lipoic Acid (LA), is an effective and safe treatment for progressive forms of multiple sclerosis.

The research team, led by Dr. Rebecca Spain, a U.S. based researcher and clinician, at Oregon Health & Science University will enroll 118 participants with progressive forms of MS across multiple sites in North America. In Canada, Dr. Mark Freedman, from the Ottawa Hospital Research Institute, will be recruiting participants for the clinical trial. Participants will be randomly assigned to either LA or placebo (mock drug) which they will take for two years.

# 2. Who will be eligible to participate in the clinical trial?

The study will recruit 118 individuals, aged greater or equal to 18 years, with a diagnosis of progressive MS and an EDSS score between 3 and 6.5. Interested participants must be able to travel to the sites where the interventions will be administered. Exclusions to participation in the study include:

- Unable to undergo MRI
- Other major diseases besides MS
- Pregnant or breastfeeding
- Self-reported medical or neurological problems other than MS that may affect gaitfunction

This is not the complete list of participation criteria. For more information please visit clinicaltrails.gov and the National MS Society website.

# 3. Which sites are recruiting participants?

There are seven (7) sites that are recruiting participants. In Canada, the Ottawa Hospital Research Institute is the only site that will be recruiting participants.

# 4. Within Canada, can people from outside of the Ottawa region participate in the clinical trial?

Individuals living outside of Ottawa region can participate but must be available for all study visits and when/if MS issues and relapses occur. Individuals would also have to pay for their own transportation and lodging to participate in the study.

### 5. Can I participate in the clinical trial?

Recruitment for the study has begun. For more information, visit our MS Update. For participation at the Ottawa Hospital, contact Dawn Carle at dcarle@toh.ca. For sites in the United States, the contact information can be found on National MS Society website and on clinicaltrials.gov

### 6. What is the intervention?

Participants are given a high dose pharmaceutical grade LA or a placebo for two years to determine whether this can reduce brain volume loss, and improve walking, quality of life and safety, in people with secondary progressive MS as compared to the placebo group (mock drug). The intervention was first tested and published in Neurology & Neuroinflammation (Published online June 28, 2017).

### 7. What are the outcome measures of the clinical trial?

The primary outcome measure for this study is mobility. Participants will be measured by the time it takes them to walk 25 meters after taking LA for two years, as compared with the time it took them to walk the same distance at the start of the clinical trial. Secondary outcome measures include the number of falls, brain atrophy as measured by magnetic resonance imaging (MRI) and any adverse side effects of the treatment.

For more information, please contact the MS Society at the msresearchgrants@mssociety.ca.