To contact the trial coordinator for more information:
Email trials@cell-innovations.com.au
Phone 1300 738 025

Background Information

Clinical study of the safety and effectiveness of Stromal Vascular Faction (SVF) stem cells in reducing the frequency and severity of chronic migraines (Cell-Innovations, Macquarie Stem Cells and Strategic Health Evaluators)

Cell-Innovations, Macquarie Stem Cells and Strategic Health Evaluators are recruiting 30 volunteers for a clinical study to test whether autologous (derived from your own body) Stromal Vascular Fraction (SVF), which consists partly of stem cells separated from your body fat, might help reduce migraine frequency and severity. In a recent case series *(see journal reference at end),* a small number of chronic migraine patients were treated with SVF. The early results of this treatment seem promising, but the effectiveness and safety of SVF needs to be tested in a greater number of patients under more controlled research conditions.

Study Details

The treatment will require 30 participants to have mini-liposuction, under local anaesthetic, to remove fat from the stomach. The SVF stem cells will be separated from the fat tissue, and participants will receive an intra-venous (IV) infusion of SVF stem cells on the day (and again 30 days later from their own stored SVF). Some participants will receive a placebo, and will still undergo liposuction, but the SVF will be stored and placebo participants will have the option of being treated one year later (free of charge).

Study Commences April 2016

The study will commence in April 2016, and will cease 12 months after the treatment of the last participant. Each participant will be screened, treated within 3 months, and monitored for 12 months after their first SVF treatment. The screening process will involve 2 consultations with a neurologist, blood tests, and completion of a headache diary for 3 months (complying with headache medication restrictions). The study treatment will be provided at no cost, and participants will be reimbursed travel expenses (up to $25 for each visit to Liverpool and Chatswood).

Participation Criteria (Minimum)

Participants must be 18 years or older, relatively healthy, and satisfy chronic migraine criteria:

1. an occurrence of a headache (tension-type and/or migraine) on more than 15 days each month for at least 3 months; and
2. headaches that last more than 4 hours.

Participation Requirements

The 30 participants will be required to attend 2 screening visits with a neurologist at Chatswood (1 hour each); a treatment visit for mini-liposuction and an IV infusion of SVF at Liverpool (4 hours); a second IV infusion of SVF at Liverpool 30 days later (2 hours); and 3 monitoring visits at Chatswood 3, 6 and 12 months after the first treatment (30 minutes each). At each visit, participants will complete questionnaires about their headaches. There will be blood tests on screening and treatment days. From the first screening visit until the final consultation (at 12 months), participants will complete a headache diary. There will be headache medication restrictions before treatment.

Research Ethics Approval

This research has been reviewed and approved by the Northern Sydney Local Health District Human Research Ethics Committee [reference HREC/15/HAWKE/279].

Contact Details

For more information contact **trials@cell-innovations.com.au** or phone **1300 738 025** to request a Participant Information Sheet detailing: the planned treatment; the benefits and risks; information on the conduct and supervision of the study; and details of the criteria to be satisfied to be eligible for the study.

Case Series Publication

Migraine and tension-type headache treated with stromal vascular fraction: a case series, Journal of Medical Case Reports 2014 8:237, http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4088303/