

# Treatment of severe chronic migraines with injections of stem cells obtained from patients' own fat tissue

<b>Submission date</b> 23/11/2016	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 02/12/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 25/09/2017	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Migraine is one of the most common neurological conditions affecting around 18% of women and 6% of men. About 2% of the population suffers from very debilitating migraines. Despite recent progress in the treatment of migraines, many sufferers cannot be helped, leading to severe disability. This study attempted to help those patients who did not respond to multiple migraine drugs and procedures, including Botox injections. Stem cells have been the subject of intensive research for the past two decades and one of the discoveries has been the strong anti-inflammatory properties of stem cells. Since migraine involves inflammation of the surface coverings of the brain, it is reasonable to assume that stem cells could relieve migraines. The richest source of stem cells in human body is fat. The aim of this study is to investigate the effectiveness treating migraine sufferers with stem cells derived from their own body fat.

### Who can participate?

Adults who suffer from long-term difficult-to-treat migraines.

### What does the study involve?

The participants in this study are asked to keep a daily headache diary starting a month before the procedure and for 3 months after it. The study procedure involves the collection of fat using standard liposuction procedures, which is then spun very quickly in a special machine (centrifuge) to separate the stem cell-rich part of fat. This is then injected into the muscles around the head and neck.

### What are the possible benefits and risks of participating?

Benefits not provided at time of registration. There are no notable risks involved with participating other than the standard risks associated with liposuction and injections into muscles, such as bruising, bleeding, infection, and cosmetic side effects.

### Where is the study run from?

New York Headache Center (USA)

When is the study starting and how long is it expected to run for?  
January 2015 to June 2016

Who is funding the study?  
MicroAire (USA)

Who is the main contact?  
Dr Alexander Mauskop  
drmauskop@nyheadache.com

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Alexander Mauskop

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
1

## Study information

**Scientific Title**  
Open label study to assess safety and efficacy of autologous adipose derived stromal vascular fraction (SVF) cells for the treatment of refractory migraine headaches

**Study objectives**  
Anti-inflammatory properties of stem cells suggest that they may be effective in the treatment of migraine headaches since neurogenic inflammation is an important part of migraine pathogenesis

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

New England Institutional Review Board, 26/06/2015, ref: 15-236

**Study design**

Open label non-randomised study

**Primary study design**

Interventional

**Secondary study design**

Non randomised study

**Study setting(s)**

GP practice

**Study type(s)**

Treatment

**Participant information sheet**

No participant information sheet available

**Health condition(s) or problem(s) studied**

Chronic migraine, refractory to treatment

**Interventions**

On all participants, liposuction is performed under local anesthesia to obtain approximately 500 ml of adipose tissue. This tissue is then centrifuged to separate stromal vascular fraction (SVF). The SVF is then injected into the pericranial muscles of the participants. The entire procedure, including the liposuction and the injections lasts for 2 to 3 hours.

All participants are followed up monthly for at least three months following the procedure.

**Intervention Type**

Biological/Vaccine

**Primary outcome measure**

Change in migraine-related disability, as measured by patient-reported Migraine Disability Assessment (MIDAS) score, in the three months following the procedure.

**Secondary outcome measures**

1. The change in impact of headaches as measured by the Headache impact score (HIT-6) in the third month compared to the month prior to the procedure
2. Patient's global impression of change is measured using a standard verbal scale at baseline and 3 months after the procedure
3. Clinician's global Impression of change is measured using a standard verbal scale at baseline and 3 months after the procedure
4. Number of headache-free days are measured using a daily diary in the month preceding the procedure and in the third month following the procedure

5. Percentage of patients with 50% or greater reduction in headache-free days is measured using a daily diary in the month preceding the procedure and in the third month following the procedure
6. Number and type of abortive migraine medications taken is measured using a daily diary in the month preceding the procedure and in the third month following the procedure

**Overall study start date**

01/01/2015

**Completion date**

20/06/2016

## Eligibility

**Key inclusion criteria**

1. Aged 18 years and over
2. Suffer from refractory chronic migraines, defined as patients with severe migraine-related disability as measured by the migraine disability assessment (MIDAS) score
3. Failed to respond to at least 3 prophylactic medications and onabotulinumtoxinA

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

10

**Key exclusion criteria**

1. Pregnancy
2. Low body mass index

**Date of first enrolment**

26/06/2015

**Date of final enrolment**

31/03/2016

## Locations

**Countries of recruitment**

United States of America

**Study participating centre**  
**New York Headache Center**  
30 East 76 Street  
New York  
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10021

## **Sponsor information**

**Organisation**  
New York Headache Center

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**Sponsor type**  
Hospital/treatment centre

## **Funder(s)**

**Funder type**  
Industry

**Funder Name**  
MicroAire

## **Results and Publications**

**Publication and dissemination plan**  
To be published in a peer-reviewed journal.

**Intention to publish date**  
31/12/2017

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are/will be available upon request from Alexander Mauskop, DrMauskop@NYHeadache.com

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	14/06/2017		Yes	No