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

Submission date
23/11/2016

Recruitment status
No longer recruiting

Registration date
02/12/2016

Overall study status
Completed

Last Edited
25/09/2017

Condition category
Nervous System Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Open label non-randomised study

Study type(s)
Treatment

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

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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
United States of America
10021

Sponsor information

Organisation
New York Headache Center

Funder(s)

Funder type
Industry

Funder Name
MicroAire

Results and Publications

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?
Results article	results	14/06/2017		Yes	No