ISRCTN13001382 https://doi.org/10.1186/ISRCTN13001382

Stromal vascular fraction cells for the treatment of critical limb ischemia

Submission date
13/04/2017

Recruitment status
No longer recruiting

Registration date
26/04/2017

Overall study status
Completed

Last Edited
21/02/2020

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Diabetes is a long-term condition is a long term condition where a person is unable to control their blood sugar (glucose) levels. Over time, high blood sugar levels can damage the arteries, affecting blood flow. If a sufferer also smokes, a fatty substance called plaque builds up inside the arteries, further cutting off blood supply. As the arteries become narrower, patients begin the feel pain even when at rest and are at severe risk of developing ulcers or gangrene (critical limb ischaemia), which in severe cases can lead to amputation. Research has shown that the use of stem cells can improve circulation and help deliver oxygen to the body's tissues but encouraging growth of new blood vessels, preventing the need or amputation. The aim of this study is to investigate the effectiveness of injecting patients with stem cells derived from their own fat tissue to treat CLI.

Who can participate?
Adult smokers with diabetic foot that is scheduled to be amputated

What does the study involve?
Participants undergo a liposuction procedure in order to collect up to 200ml of fat. This is then used to isolate stem cells in the laboratory. Participants then attend a study visit during which the stem cells are injected into the problematic limb. Following the injections, patients are regularly asked to rate their pain levels. At the start of the study and then after two weeks and two, six, 12 and 24 months, patients have a scan to find out whether any new blood vessels have formed and complete a walking test to find out if the symptoms of the CLI have improved and they are able to walk further.

What are the possible benefits and risks of participating?
Participants may benefit from receiving the stem cell treatment but this is not guaranteed. There is a small risk of pain following fat collection and stem cell injections.

Where is the study run from?
Vilnius City Clinical Hospital (Lithuania)

When is the study starting and how long is it expected to run for?
January 2015 to January 2018

Who is funding the study?
JSC Froceth (Lithuania)

Who is the main contact?
Mr Adas Darinskas
adas@froceth.lt

Contact information

Type(s)
Scientific

Contact name
Mr Adas Darinskas

ORCID ID
http://orcid.org/0000-0002-1916-7535

Contact details
JSC Froceth
Linkmenu 28
Vilnius
Lithuania
LT-10104
+370 (0)61 608 734
adas@froceth.lt

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
SOP2014FRCH10SVF001CLI

Study information

Scientific Title
Stromal vascular fraction cells for the treatment of critical limb ischemia

Acronym
SVF for CLI

Study objectives

Stromal vascular fraction cells are able to induce novel neovascularisation of lost vessels by arteriosclerosis and ischemia process.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Due to Lithuanian law, for non manipulated autologous tissues we do not need ethics approvals as it is completely legal to perform these procedures for critical diseases and conditions based on medical procedure description. The law which legalises these applications of autologous cells is approved by Lithuanian Ministry of Health, 2014 December 2nd, the number of the document is V-1248. All procedures and protocols are introduced into the mentioned hospital (we have performed treatments) and all the legal issues are completely solved

Study design
Interventional non-randomised study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Critical limb ischemia

Interventions
All participants undergo lipoaspiration in the hospital by plastic surgeon. This involves up to 200ml of lipoaspirate being collected so that stem cells can be isolated in the GMP qualified laboratory and registered into national stem cell tissue bank registry. Patients then undergo multiple stem cell injections into the problematic limb.

Every 24 hours following the injections, patients are regularly asked to rate their pain levels. In addition, at baseline and then after two weeks and two, six, 12 and 24 months, patients undergo an anghiography and complete a walking test to assess claudication.

Intervention Type
Biological/Vaccine

Primary outcome measure

Pain is measured using the visual analogue scale (VAS) at baseline, 24, 48 and 72 hours post multiple injections.

Secondary outcome measures
1. Neovascularisation process is measured using angiography at baseline, 2 weeks, 2, 6, 12 and 24 months
2. Claudication index is assessed using a functional distance measurement test at baseline, 2 weeks, 2, 6, 12 and 24 months respectively

Overall study start date
01/01/2015

Completion date
01/01/2018

Eligibility

Key inclusion criteria
1. Smokers
2. Diabetic feet
3. Poor vascularisation of the limb
4. Prescribed amputation
5. Aged 18 years and over

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
15

Key exclusion criteria
1. Pregnancy
2. Age below 21

Date of first enrolment
01/02/2015

Date of final enrolment
01/06/2015

Locations

Countries of recruitment
Lithuania

Study participating centre
Vilnius City Clinical Hospital
Antakalnio str. 57, Vilnius, Lithuania
Vilnius
Lithuania
LT-10104

Sponsor information

Organisation
JSC Froceth

Sponsor details
Linkmenu 28
Vilnius
Lithuania
LT-08217
+370 (0)61 608 734
info@froceth.lt

Sponsor type
Charity

Website
http://www.audiniubankas.lt

ROR
https://ror.org/04tgkyt11

Funder(s)

Funder type
Charity

Funder Name
JSC Froceth

Results and Publications

Publication and dissemination plan
Planned publication of study results in the Journal of Translational Medicine.

Intention to publish date
13/04/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Agne Vaitkeviciene (agne@froceth.lt)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	19/06/2017		Yes	No