

Stromal vascular fraction cells for the treatment of critical limb ischemia

Submission date 13/04/2017	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 26/04/2017	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 21/02/2020	Condition category Circulatory System	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Diabetes 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 to 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 for 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

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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 angiography and complete a walking test to assess claudication.

Intervention Type

Biological/Vaccine

Primary outcome(s)

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

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

ROR

<https://ror.org/04tgkyt11>

Funder(s)**Funder type**

Charity

Funder Name

JSC Froceth

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 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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes