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Foam sclerotherapy for venous leg ulcers

Submission date
13/04/2022

Recruitment status
No longer recruiting

Registration date
25/04/2022

Overall study status
Completed

Last Edited
11/04/2025

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Venous leg ulcers are the commonest type of ulcers affecting the legs. They are caused by obstruction of the veins as a result of previous thrombosis (blood clot), or by reflux of the venous valves (reversal of blood flow), which may be either present from birth or caused by previous thrombosis. In addition to the standard care of venous leg ulcers which includes wound care, treatment of the underlying venous pathology (disease), and appropriate compression therapy, foam sclerotherapy of the refluxing veins around the ulcers has been used for more than 10 years by many physicians, who reported improved outcomes in terms of time to achieve complete ulcer healing. The aim of this study is to compare standard treatment versus standard treatment in addition to foam sclerotherapy of the refluxing veins in the vicinity of the ulcer.

Who can participate?
Patients with open venous leg ulcers with underlying venous pathology and refluxing veins near the ulcer

What does the study involve?
Participants are randomly allocated into two groups. One group will receive standard treatment only, while the other group will receive foam sclerotherapy of the veins around the ulcer in addition to standard treatment. The foam sclerotherapy treatment is applied once and could be repeated one more time if necessary.

What are the possible benefits and risks of participating?
Participants will be treated by experts in the field and will receive the standard care for venous leg ulcers. Those who are in the foam sclerotherapy group may benefit from more rapid healing of the ulcers. The risks are minimal and include the potential side effects of foam sclerotherapy.

Where is the study run from?
The study is performed in outpatient service facilities in multiple centers in Egypt.

When is the study starting and how long is it expected to run for?
September 2021 to December 2024

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Rashad Bishara
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Contact information

Type(s)
Principal Investigator

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Dr Rashad Bishara

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
RCT2022-1

Study information

Scientific Title
Randomized controlled trial of foam sclerotherapy for venous leg ulcers

Acronym
FoVLU

Study objectives
Foam sclerotherapy of refluxing veins in the vicinity of the venous leg ulcer promotes healing and reduces the time to complete ulcer healing.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/02/2022, Ethical Committee of the General Organization of Teaching Hospitals (GOTHI; Dr Nagham Al-Amir, 16 Kasr Al-Aini Street, Sayeda Zeinab, Cairo 11617, Egypt; +20 (0) 1005181311; dr_alamir@hotmail.com), ref: IDE00274

Study design
Multicenter prospective randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Written in Arabic (local language)

Health condition(s) or problem(s) studied
Venous leg ulcers

Interventions
An electronic random number generator application is used for randomization. Eligible patients presenting with open venous leg ulcers who show evidence of underlying venous pathology on duplex scan will be randomized into two groups:
Group A will be treated by foam sclerotherapy of the refluxing venous plexus in the vicinity of the ulcer, in addition to standard care for venous leg ulcers. The treatment is applied once and could be repeated one more time if necessary.
Group B will receive standard care for venous leg ulcers only.

Standard care for venous leg ulcers may include, ablation or stripping of superficial venous reflux, phlebotomy or foam sclerotherapy of incompetent tributaries, recanalization and stenting of occluded iliac veins, wound care, and appropriate compression therapy.

Every patient will be treated until the ulcer heals or until the end of the trial. The duration of follow up is a minimum of 6 months, up to 12 months.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Time to complete venous leg ulcer healing measured by photography at weekly time intervals after the application of the treatment until healing

Secondary outcome measures
1. Venous leg ulcer healing measured by Lesionmeter software and photography at weekly intervals after the application of treatment until complete ulcer healing
2. Ulcer recurrence assessed by telephone follow up at monthly intervals after complete venous leg ulcer healing for a minimum of 6 months, and a maximum of 12 months
3. Ulcer-free time assessed by telephone follow up at monthly intervals after complete venous leg ulcer healing for a minimum of 6 months and a maximum of 12 months
4. Health-related quality of life assessed using the SF12 questionnaire before the start of treatment and at complete ulcer healing
5. Side effects of foam sclerotherapy assessed by patient history and physical examination during the follow-up visit in the week following the application of treatment
6. Outcome measured using the Venous Clinical Severity Score (VCSS) once before entering into the study, and once after complete ulcer healing, or at the end of the trial

Overall study start date
01/09/2021

Completion date
31/12/2024

Eligibility

Key inclusion criteria
1. Patients with active venous leg ulceration, classified as C6 in the CEAP classification
2. Have duplex or venography criteria of primary superficial venous reflux, or criteria of post-thrombotic deep venous reflux and/or obstruction
3. Show a refluxing network of veins in the vicinity of the ulcer; “ulcer veins”, and/or pathologic incompetent perforators

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
130

Total final enrolment
77

Key exclusion criteria
1. Pregnant and lactating females
2. Age <18 years
3. Peripheral arterial disease confirmed by ABPI <0.8, or a duplex scan showing significant peripheral arterial disease

4. Do not show evidence of a refluxing network of veins in the vicinity of the ulcer; “ulcer veins”
5. VLU >2 years duration
6. VLU size >20 cm in any dimension
7. Participant unable to give informed consent

Date of first enrolment
15/01/2022

Date of final enrolment
30/12/2023

Locations

Countries of recruitment
Egypt

Study participating centre
Rashad Bishara
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Egypt
11221

Study participating centre
Wassila Taha
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11221

Study participating centre
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Sponsor information

Organisation
Organization of Teaching Hospitals and Institutes (GOTHI)

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Sponsor type
Government

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Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in high-impact peer-reviewed journals

Intention to publish date
30/06/2025

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			20/04/2022	No	No
Protocol file			17/10/2022	No	No
Results article		08/04/2025	11/04/2025	Yes	No