

# Foam sclerotherapy for venous leg ulcers

<b>Submission date</b> 13/04/2022	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 25/04/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 11/04/2025	<b>Condition category</b> Circulatory System	<input type="checkbox"/> 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  
rashadbishara@gmail.com

## Contact information

### Type(s)

Principal investigator

### Contact name

Dr Rashad Bishara

### ORCID ID

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Protocol serial number

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

## **Study type(s)**

Treatment

## **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, phlebectomy 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(s)**

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

## **Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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**

Cairo

Egypt

11221

**Study participating centre**

**Wassila Taha**

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Egypt

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**Study participating centre**

**Ahmed Gaweesh**

Alexandria

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**Study participating centre**

**Ahmed Khairy**

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**Sherif Essam**  
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## Sponsor information

**Organisation**  
Organization of Teaching Hospitals and Institutes (GOTHI)

## Funder(s)

**Funder type**  
Other

**Funder Name**  
Investigator initiated and funded

## Results and Publications

### 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?
<a href="#">Results article</a>		08/04/2025	11/04/2025	Yes	No
<a href="#">Protocol file</a>			20/04/2022	No	No
<a href="#">Protocol file</a>			17/10/2022	No	No