

**Participant Information Sheet**

**Surgical glue for the treatment of damaged veins**

**in people with leg ulcers.**

**Scientific title:** Pilot study of cyanoacrylate occlusion of the lower limb veins in patients with venous leg ulcers. IRAS Project ID 232234.

**How to contact us**

If you have any questions about this study, please contact us via the following:

**Contact name:**

Mr David Riding (Research Fellow)

**Telephone:**

0161 291 5842

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david.riding@manchester.ac.uk

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**1. We invite you to take part in a research study**

* Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve
* Please take the time to read to the following information carefully. Discuss it with friends and relatives if you wish.
* You are free to decide whether or not to take part in the trial. If you decide not to take part, this will not affect the care you receive in any way.
* Please ask if there is anything that is unclear or if you require other information.

**2. Important things you need to know**

* We are trying to establish whether treating damaged veins with surgical glue reduces the time taken for a venous leg ulcer to heal. This is the type of ulcer that you have been diagnosed with.
* We will do this by randomly allocating half of all patients to receive the glue treatment, and half to receive standard treatment. This is a common way to determine whether a treatment might be effective.
* There are some potential side effects associated with the surgical glue treatment, but these are rare. They are described in Section 6.
* This study is a collaboration between doctors at the University Hospital of South Manchester and Medtronic, a company who develop medical devices, including the surgical glue and the equipment required to perform the procedure. The study is fully funded by Medtronic.

**If you remain interested in taking part, the rest of the information sheet gives more detail about the study**

**3. Why is this study being carried out?**

Leg ulcers are painful, can cause dangerous systemic infections, and the treatment can be difficult to endure. Therefore, treatments that reduce the time taken for the ulcer to heal are needed. Some ulcers are caused by blood flowing the wrong way down the long veins of the leg, usually as a result of poorly functioning valves. We know that the usual treatment of compression bandages, wound care and assessment by a specialist leg ulcer nurse helps ulcers to heal. **We do not know whether treatment with surgical glue helps ulcers to heal faster, or slower, or no differently than with the usual treatment alone. That is why we will randomly allocate patients to one of the two groups.**

There has not been any research into the use of surgical glue for this purpose, though other studies have shown that it is a safe, effective treatment for varicose veins of the leg, which are also caused by damaged valves. The results of this study will help us to establish whether the surgical glue is also effective for the treatment of leg ulcers.

You are being invited to participate as you have a leg ulcer that has arisen as a result of damaged veins in the leg. We are inviting all patients with this type of ulcer to undergo a simple ultrasound scan to determine whether their damaged veins would be suitable for the surgical glue treatment. We need 55 patients in total to agree to take part in the study.

**4. What happens if I agree to take part?**

One of the important aspects of this study is that half the patients will be randomly allocated to receive the surgical glue treatment, and half will not. All patients will receive the usual care for their leg ulcer.

All patients agreeing to take part in the study will be invited to attend hospital for an ultrasound scan of their leg veins. This is done to make sure that they are suitable for the surgical glue treatment. At this point, patients with veins that are not suitable will not take any further part in the study, but will continue to receive the usual care for their leg ulcer.

At this point, patients with suitable veins will be randomly allocated to receive usual care, or usual care and the surgical glue procedure.

Patients randomly allocated to receive the surgical glue treatment will be asked to return at 3, 6 and 12 months after their procedure to undergo further ultrasound scans. At these appointments, they will also be asked to complete a questionnaire asking them about their symptoms. Patients randomly allocated to usual care only will be asked to complete the same questionnaires by post or online.

The diagram on the next page summarises what will happen during the study.

**Study ends after 12 months**

**All patients will be asked to do the following at 3, 6 and 12 months after being in the study:**

Ultrasound scan at the hospital (if randomly allocated to receive the surgical glue treatment)

Complete a written questionnaire at home (or in person whilst attending hospital for the scan)

**All patients will attend weekly leg ulcer clinic appointments until their ulcer has completely healed.**

Here, they will receive usual care:

Compression bandaging

Wound care

Specialist nurse / doctor review

Usual care

Usual care

Surgical glue treatment

Scan shows veins are not suitable for the glue treatment.

Return to usual care.

Scan shows veins are suitable for the glue treatment.

Randomly allocated to receive the surgcial glue treatment and usual care, or just usual care.

Attend hospital for ultrasound scan.

Patient attends leg ulcer clinic. Agrees to take part and completes consent form.

**5. What does the procedure involve?**

Of all the patients agreeing to take part, half will be randomly allocated to receive the surgical glue treatment. The glue blocks the damaged vein, preventing blood from flowing the wrong way down it. The procedure is as follows:

1. You may feel some minor pain or stinging as a local anaesthetic injection is used to numb the site where the surgeon will access your vein.

2. Once the area is numb, the surgeon will insert a catheter (i.e., a small hollow tube) into your leg vein. You may feel some pressure as the catheter is placed.

3. The catheter will be placed in specific areas along the diseased vein to deliver small amounts of the surgical glue. You may feel a mild sensation of pulling or tugging. The surgeon will use an ultrasound scanner during the procedure to guide and position the catheter correctly

4. After treatment, the catheter is removed and a dressing is placed over the puncture site.

5. It is expected that patients will return to normal activity immediately after the procedure.

You will usually need to spend around 3-4 hours in hospital for pre- and post-procedural checks and monitoring. The procedure itself takes between 30 and 60 minutes.

**6. Are there any risks or benefits?**

There are no benefits to taking part in this study. Participating in research like this means that you are helping to generate new evidence that can justify developing and improving treatment for those who will develop leg ulcers in future.

Like any medical treatment, the surgical glue procedure has some risks associated with it. These include:

Allergic reaction

Bleeding

Abnormal connection between an artery and vein (‘fistula’)

Blood clot in the deep veins (‘deep vein thrombosis’)

Swelling of the leg

Darkening of the skin (‘hyperpigmentation’)

Infection

Pain

Numbness around the area where the needle is introduced

Inflammation of the veins (‘phlebitis’)

Blood clot in one of the arteries in the lung (‘pulmonary embolism’)

Scarring

Surgical glue is licensed for use in the United Kingdom, and the risk of serious complications is very low. In a study of 70 patients receiving surgical glue to treat varicose veins, inflammation of the vein occurred in 11.4% of participants (average duration 6 1/2 days), and pain was experienced by 8.6% (average duration 1 day). There were no serious side effects reported.

Patients should also be reassured that all personal data will be stored securely, in line with NHS guidelines. The data will be stored on University of Manchester computers, and all paper documents will be stored in a locked cabinet inside a lockable room, at Wythenshawe Hospital. The data will be stored for 5 years after the completion of the study, after which time they will be destroyed.

**Copies of fully anonymised ultrasound scan images may be used by Medtronic, the company who developed the surgical glue, for educational and marketing purposes. If you do not agree to their use for this purpose, please inform the research team. This does not prevent you from taking part. All data will be anonymised before leaving the NHS Trust.**

**7. How do I leave the study?**

You may leave the study at any time by contacting the research team (details below). You do not have to give a reason for leaving the study, nor will it affect the usual care you receive for the study.

If you wish to leave the study, or if you have any other concerns or queries, please contact

**Mr David Riding** (Clinical Research Fellow at University Hospital of South Manchester).

**Telephone: 0161 291 5842** (office hours)

**Email: david.riding@manchester.ac.uk** (any time)

**8. Can I claim expenses?**

You may claim travel expenses back from the hospital by completing a simple form. This will be offered to you when you complete the consent form in the clinic. Please forward any expenses claim forms by email to:

david.riding@manchester.ac.uk

or by post to:

Mr David Riding

Academic Surgery Unit

2nd Floor ERC

University Hospital of South Manchester

M23 9LT

**Contact for independent advice:**

If you require independent advice about this study, either before, during or after its completion then please contact the Patient Advice and Liaison Service at Wythenshawe Hospital. This service is run independently of the staff involved in the study:

Telephone: 0161 291 5600/2031/2033

Email: pals@mft.nhs.uk

In person: PALS is located on the Ground Floor of Wythenshawe Hospital adjacent to the outpatient clinic check in desk, accessed via Entrance 5.