

# Venous Pressure Monitoring in Patients Undergoing Foam Sclerotherapy

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<b>Registration date</b> 29/09/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 16/11/2017	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
645/09

## Study information

**Scientific Title**  
Continuous Ambulatory Venous Pressure Monitoring and the Results of Foam Sclerotherapy in the Lower Limb

### Study objectives

1. Primary: To quantify and assess the venous pressure-lowering effect of Foam Sclerotherapy in patients with lower limb superficial venous reflux and to compare the venous pressures with

patients' activity profiles.

2. Secondary: To assess changes in quality of life associated with foam sclerotherapy treatments

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Newcastle and North Tyneside 1 Research Ethics Committee (REC) – submission pending (ref:10/H0906/37)

### **Study design**

Multicentre observational cohort trial

### **Primary study design**

Observational

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Varicose veins

### **Interventions**

1. Recruitment:

Patients will be recruited from outpatient clinics held at the Queen Elizabeth Hospital and Freeman Hospital. Three patient groups, determined by the anatomical site of venous reflux will be identified for the study:

- 1.1. Varicose veins with truncal long saphenous (LSV) incompetence
- 1.2. Varicose veins with truncal short saphenous (SSV) incompetence
- 1.3. Varicose veins with combined truncal LSV and SSV incompetence

Patients from the out patient clinic who have been listed for foam sclerotherapy as treatment for their varicose veins, and who fulfil the inclusion criteria will be invited to take part in the study.

These patients will have had a duplex scan as part of their normal work up for varicose vein treatment, and this will determine the sites of venous reflux. Those patients taking part in the study will be invited to attend at a separate visit in order to do venous pressure and activity measurements.

Patients who have agreed to take part in the study and who fulfil the inclusion criteria will be asked to attend the hospital (Freeman or Queen Elizabeth Hospital) for investigations prior to their foam sclerotherapy treatment and again following treatment.

2. Monitoring:

At each of these visits the following will be performed:

2.1. Continuous Ambulatory Venous Pressure Monitoring (CAVPM)

Local anaesthetic will be injected into the skin or emla cream applied at the site of proposed cannula insertion. A 20- gauge PTFE venflon cannula will be inserted into the LSV at the level of the ankle. This will be connected to a pressure transducer and pressure monitoring kit (Novatrans MX860 and MX8004 respectively) and the transducer will be attached to the leg at a predetermined height above the lateral malleolus. Patency of the cannula will be maintained by a continuous heparinised saline flush (concentration 10 units/ml) infused by a syringe driver (MS

16A, Sims Graseby Ltd). The transducer will then be attached to the CAVPM system, which will consist of a palm to Psion organiser II data logger and sf12 software (digitron instrumentation). Attached to the data logger via a cable will be a signal amplifier. The SF12 software processes signals from the amplifier, it drives the data logger and connects the data logger to the Psion Organiser II where data will be stored.

2.1.1. The venous pressure will then be measured during the following activities:

2.1.1.2. Lying, sitting, and standing

2.1.1.3. During and after 10 tiptoe exercises

2.1.1.4. Continuously during walking at a steady pace on a treadmill for a period of up to 20-30 minutes, depending on the patient's capacity for walking.

2.1.2. From these measurements the following data will be obtained:

2.1.2.1. Mean pressure supine, sitting and standing

2.1.2.2. Mean minimum lower limb venous pressure achieved during walking

2.1.2.3. Mean lower limb venous pressure achieved during walking

2.1.2.4. Rates of change of pressure (RCP) with change in posture

2.2. Activity Monitoring (Newcastle Medical Activity Monitor System [NUMACT])

A (non-invasive) NUMACT device will be used. This entails attaching a position sensor to the chest and accelerometer sensor to the lateral aspect of the lower limb being studied. These sensors are connected to a Psion 3 series palmtop computer via an interface module, which the signals from the sensors and provides a high-speed serial data link to the palmtop. The patient can wear this equipment around their waist. The patients will leave the hospital wearing these sensors and will be asked to go about their normal daily activities to permit recordings to be taken over a period of 24 hours. After this they will be reviewed in hospital to remove the recording devices.

The following will be recorded by this method:

2.2.1. Activity profiles during the 24 hour period

2.2.2. The time spent in various positions (supine, sitting, standing)

2.2.3. The time spent performing activities and the step amplitude.

The patient will have a duplex scan before and 6 weeks after the foam sclerotherapy as part of the clinical work up. The CAVPM and NUMACT measurements will performed before and after the foam sclerotherapy.

## **Intervention Type**

Device

## **Primary outcome(s)**

To quantify and assess the venous pressure-lowering effect of Foam Sclerotherapy in patients with lower limb superficial venous reflux and to compare the venous pressures with patients' activity profiles. These measurements will be performed using a Continuous Ambulatory Venous Pressure Monitoring device and a NUMACT system

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

To assess changes in quality of life associated with foam sclerotherapy treatments using the Aberdeen Varicose Vein Questionnaire.

## **Completion date**

14/10/2012

# Eligibility

## Key inclusion criteria

1. Patients with long or short saphenous venous reflux
2. Patients with varicose veins belonging to any of the clinical classes of Clinical, Etiologic, Anatomic and Pathophysiologic (CEAP) classification C2, C3, C4, C5 and C6
3. Patients with a full range of movement of the joints in both their lower limbs
4. Patients who are freely mobile with no mechanical aid assisting their movement
5. Aged 18 - 75

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Adult

## Lower age limit

18 years

## Sex

All

## Key exclusion criteria

1. Patients belonging to CEAP Ec, Po and Po & R or with past history of Deep Vein Thrombosis (DVT) or pulmonary embolism
2. A history suggestive of deep venous obstruction
3. Peripheral arterial disease
4. Anticoagulation therapy
5. Serious systemic diseases such as angina, myocardial infarction, asthma, COAD, CCF, hepatic failure and renal failure
6. Pregnancy
7. Any patient with heparin allergy
8. Patients unable to give consent

## Date of first enrolment

15/10/2010

## Date of final enrolment

14/10/2012

# Locations

## Countries of recruitment

United Kingdom

England

**Study participating centre**  
**Queen Elizabeth Hospital**  
Gateshead  
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## **Sponsor information**

**Organisation**  
Gateshead Health NHS Foundation Trust (UK)

**ROR**  
<https://ror.org/01aye5y64>

## **Funder(s)**

**Funder type**  
Government

**Funder Name**  
Gateshead Health NHS Foundation Trust (UK)

## **Results and Publications**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**  
Not provided at time of registration