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Venous Pressure Monitoring in Patients Undergoing Foam Sclerotherapy

Submission date 22/09/2010	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 29/09/2010	**Overall study status** Completed	
Last Edited 16/11/2017	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr Tarig Barakat

Contact details
Queen Elizabeth Hospital
Gateshead
United Kingdom
NE9 6SX

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet

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 measure
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

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

Overall study start date
15/10/2010

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
36

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 patent 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
England

United Kingdom

Study participating centre
Queen Elizabeth Hospital
Gateshead
United Kingdom
NE9 6SX

Sponsor information

Organisation
Gateshead Health NHS Foundation Trust (UK)

Sponsor details
Queen Elizabeth Hospital
Gateshead
England
United Kingdom
NE9 6SX

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01aye5y64

Funder(s)

Funder type
Government

Funder Name
Gateshead Health NHS Foundation Trust (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration