Clinical trial results:
A Randomised Controlled Trial of Tumescent Anaesthesia in addition to Surgical Ligation and Stripping of the Great Saphenous Vein.

Summary

EudraCT number	2011-005574-39
Trial protocol	GB
Global end of trial date	30 January 2015

Results information

Result version number	v1 (current)
This version publication date	18 December 2019
First version publication date	18 December 2019
Summary attachment (see zip file)	A randomised controlled trial of perivenous tumescent anaesthesia in addition to general anaesthesia for surgical ligation and stripping of the great saphenous vein (R1268 A randomised controlled trial of perivenous tumescent anaesthesia in addition to general anaesthesia for surgical ligation and stripping of the great saphenous vein.pdf)

Trial information

Trial identification

Sponsor protocol code	Surgery&TumescenceV3

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Hull University Teaching Hospitals NHS Trust
Sponsor organisation address	Anlaby Road, Hull, United Kingdom, HU3 2JZ
Public contact	Mr Tom Wallace, Academic Vascular Surgical Unit, Hull Royal Infirmary, +44 07789913071, tom.wallace@hey.nhs.uk
Scientific contact	Mr Tom Wallace, Academic Vascular Surgical Unit, Hull Royal Infirmary, +44 07789913071, tom.wallace@hey.nhs.uk

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	29 October 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	16 October 2014
Global end of trial reached?	Yes
Global end of trial date	30 January 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The aim of this study is to evaluate the use of perivenous local anaesthesia during open SFJ ligation and GSV stripping. The hypothesis is that this could be associated with improvements in pain, QoL, and recovery to normal activities.

Protection of trial subjects:

Full information about the study is shared in advance via the patient information sheet and participation is entirely voluntary. Ethics approval has been obtained.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	11 October 2012
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United Kingdom: 90
Worldwide total number of subjects	90
EEA total number of subjects	90

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	82
From 65 to 84 years	8
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Prior to introduction of UK NICE guidance CG168, patients were offered the intervention either endothermal ablation or surgery. Subsequent to July 2013, participants were offered surgery at surgeon or patient preference in a non-trialist clinic, where the anatomy was not favourable for endovenous procedure or guided by patient choice.

Pre-assignment

Screening details:

Inclusion criteria included adults with primary symptomatic SVI, CEAP grades C2–C6, suitable to undergo open surgical ligation and GSV stripping on Duplex ultrasound (DUS) assessment. Incompetence was defined as reflux of at least 0.5 s on spectral Doppler analysis

Period 1

Period 1 title	Baseline (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind
Roles blinded	Subject

Blinding implementation details:

Patients were randomised by an online digital randomisation programme (www.sealedenvelope.com) after invitation to participate and prior to the procedure. The outcome of the randomisation was concealed from the participant. Patients were randomised to either a standard open surgical procedure under General Anaesthesia (GA) (GA Group) or to the addition of tumescent (G þ T group) once they had been listed for surgical management.

Arms

Are arms mutually exclusive?	Yes
Arm title	GA Alone

Arm description:

A standard open surgical procedure under General Anaesthesia (GA) (GA Group)

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	GA Plus Tumescent

Arm description:

Under General Anaesthesia (GA) with the addition of tumescent (G & T group)

Arm type	Active comparator
Investigational medicinal product name	PR1 1% Lidocaine (Xylocaine) with 1:200,000 epinephrine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Infiltration

Dosage and administration details:

The solution was made up of 900 ml of 0.9% sodium chloride solution with 100 ml of 1% lidocaine with 1:200,000 epinephrine added. Each bag of tumescent anaesthesia was for single-use only. The anaesthesia was administered using a pedaloperated peristaltic pump (Nouvag DP-20, Nouvag, Goldach, Switzerland) along the GSV (with PIN stripper in situ) with the use of DUS guidance, at a target of 10 ml per cm. Tumescent anaesthesia was also infiltrated into the groin incision and around all tributaries and perforators to be treated, this was performed by the operating surgeon, competent in DUS and endovenous ablative techniques. Patients in the control group received local anaesthesia consisting of 1% lidocaine with 1:200,000 epinephrine to the groin incision and stripper exit site only as per standard practice.

Number of subjects in period 1	GA Alone	GA Plus Tumescent
Started	45	45
Completed	45	45

Baseline characteristics

Reporting groups	
Reporting group title	GA Alone
Reporting group description:	
A standard open surgical procedure under General Anaesthesia (GA) (GA Group)	
Reporting group title	GA Plus Tumescent
Reporting group description:	
Under General Anaesthesia (GA) with the addition of tumescent (G & T group)	

Reporting group values	GA Alone	GA Plus Tumescent	Total
Number of subjects	45	45	90
Age categorical Units: Subjects			
Adults (18-64 years)	42	40	82
From 65-84 years	3	5	8
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	28	29	57
Male	17	16	33

End points

End points reporting groups

Reporting group title	GA Alone
Reporting group description:	
A standard open surgical procedure under General Anaesthesia (GA) (GA Group)	
Reporting group title	GA Plus Tumescent
Reporting group description:	
Under General Anaesthesia (GA) with the addition of tumescent (G & T group)	

Primary: The bodily pain (BP) domain of SF-36 QoL tool

End point title	The bodily pain (BP) domain of SF-36 QoL tool[1]
End point description:	
End point type	Primary
End point timeframe:	
1 week	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Full Publication with results including statistical analysis included.

End point values	GA Alone	GA Plus Tumescent		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	45	45		
Units: 0-100				
number (not applicable)	45	45		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

Investigators will notify HEY R&D of serious adverse events within 24hrs. HEY R&D will report fatal or life-threatening SUSARs to the MHRA within 7days and follow-up information within a further 8 days.

Adverse event reporting additional description:

Adverse events will be reported in accordance with Hull and East Yorkshire Hospitals NHS Trust R&D (HEY R&D) Safety Reporting standard operating procedure (R&D GCP SOP 09) to ensure compliance with UK Clinical Trial Regulations.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	17

Frequency threshold for reporting non-serious adverse events: 1 %

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: Final published results attached.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported