



Clinical trial results:

A Randomised Controlled Trial of Tumescant 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 Tumescant |
|---------------------------------------|----------|-------------------|
| 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 Tumescant |
|-----------------------|-------------------|

Reporting group description:

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

| Reporting group values | GA Alone | GA Plus Tumescant | 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 Tumescant |
| 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 Tumescant | | |
|-----------------------------|-----------------|-------------------|--|--|
| 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