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Assessment of cost-effectiveness of the treatment of varicose veins

Submission date	Recruitment status	[ ] Prospectively registered
25/04/2003	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
25/04/2003	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
08/11/2022	Circulatory System	

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
HTA 95/05/06

Study information

Scientific Title
Assessment of cost-effectiveness of the treatment of varicose veins

Acronym
REACTIV

Study objectives
The project will assess the cost effectiveness of the commonly used treatments for Varicose Veins by way of Markov process decision model. The data for the modelling will be obtained through a combination if systematic literature review and the collection of retrospective and prospective data on patients undergoing treatment for varicose veins. This will include randomised controlled studies in three sub-groups of patients in whom conservative treatment, sclerotherapy and surgery will be compared.
The model will allow an assessment of the incremental cost effectiveness of each treatment modality in sub groups of patients based upon their symptomatic, investigative and demographic features. Patient and societal priorities for treatment will be assessed using a "willingness to pay" (WTP) technique.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added as of 25/07/2007: Ethical approval for the study was obtained from both Sheffield and Exeter Local Research Ethics Committees.

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
Varicose veins/ulcers

Interventions
Interventions updated as of 25/07/2007:
Group 1 (34 patients): minor varicose veins with no reflux, randomised between conservative treatment and sclerotherapy
Group 2 (77 patients): moderate varicose veins with reflux, randomised between surgery and sclerotherapy
Group 3 (246 patients): severe varicose veins with reflux, randomised between conservative treatment and surgery

The remaining 652 patients formed the observational part of the study.

Interventions provided at time of registration:
1. Conservative treatment
2. Sclerotherapy
3. Surgery

Intervention Type

Other

Phase
Not Specified

Primary outcome(s)
Primary outcome measures updated as of 25/07/2007:
1. Clinical effectiveness, as measured using the Short Form 6D (SF-6D) utility valuation
2. Cost-effectiveness analysis

Primary outcome measures provided at time of registration:
Cost-effectiveness of each treatment

Key secondary outcome(s))
Added as of 25/07/2007:
1. Complications of treatment
2. Symptomatic relief
3. Health-Related Quality of Life (HRQoL) and patient satisfaction. HRQoL was measured using the Short Form with 36 Items (SF-36), EuroQol quality of life questionnaire (EQ-5D) and standard gamble questionnaires.

Completion date
30/09/2003

Eligibility

Key inclusion criteria
Patients undergoing treatment for varicose veins

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Added as of 25/07/2007:

General exclusion criteria:
1. Unwillingness to give informed consent
2. Unwilling or unable to complete assessment protocol
3. Current evidence of thrombophlebitis, ulceration or DVT

Specific exclusion criteria:

Group 1 Sclerotherapy vs conservative treatment:
1. Patients with deep venous insufficiency confirmed by duplex
2. Allergy to sclerosant
3. Diameter of varicose veins >2 cm

Group 2 Sclerotherapy vs surgery:
1. Patients with deep venous insufficiency confirmed by duplex
2. Allergy to sclerosant
3. Diameter of varicose veins >2 cm
4. Pre-existing co-morbidities that would make them unsuitable for surgery
5. BMI >32

Group 3 Surgery vs conservative treatment:
1. Patients with deep venous insufficiency confirmed by duplex
2. Allergy to sclerosant
3. Diameter of varicose veins >2 cm
4. Pre-existing co-morbidities that would make them unsuitable for surgery.
5. BMI >32

Date of first enrolment
01/10/1998

Date of final enrolment
30/09/2003

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Department of Vascular Surgery
Sheffield
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Sponsor information

Organisation
Department of Health (UK)

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK)

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	HTA monograph	01/04/2006		Yes	No