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Randomised controlled trial of surgical treatment of varicose veins in legs: Stripping versus Conservative Treatment (CHIVA)

Submission date
05/03/2005

Recruitment status
No longer recruiting

Registration date
13/04/2005

Overall study status
Completed

Last Edited
04/01/2016

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Varicose veins are swollen and enlarged veins that usually occur on the legs. The condition is highly common and causes a wide range of problems and complications, such as inflammation of the veins, formation of blood clots, and ulcers in some more extreme cases. As a result of several of the conditions mentioned above, patients visit specialists in search of solutions; vascular surgeons generally recommend surgery when necessary. Patients must be made aware that, as the disease is chronic, they can never be healed, and after surgical treatment, varicose veins may appear again some years later (between 20 and 80% of patients over a 5-year period). For over a hundred years, varicose veins have been surgically treated using destructive techniques. Standard practice involves the removal of all diseased veins. Stripping has been the routine procedure applied, in addition to other techniques which were developed later, which include laser, radiofrequency and sclerosis procedures. Hemodynamic Ambulatory Conservative Management of Varicose Veins (CHIVA in French) is a surgical treatment that aims to treat varicose veins without destroying the venous system, and so preserve its functions. Preserving the main vein in the leg, the internal saphenous vein, is also necessary if the patient concerned requires heart or leg arterial surgery. The treatment of reappearing varicose veins after an initial surgical operation using the CHIVA method is much simpler when compared with the treatment with other destructive techniques, which is anatomically more complex. This study was undertaken to find out whether the recurrence of varicose veins is lower after surgery using the CHIVA method compared with stripping.

Who can participate?
Adult patients (18 or older) with primary varicose veins in the legs.

What does the study involve?
Patients are randomly allocated into three groups to be treated with one of three different methods: Stripping Clinic Mapping, Stripping Duplex Mapping or CHIVA. Ultrasounds and clinical follow-up procedures are scheduled for the three groups at 3, 6, 12, 24, 36, 48, 60 and 120 months after surgery.

What are the possible benefits and risks of participating?
As a safety measure, any major complications are evaluated 8 days after the operation.

Where is the study run from?
This study takes place in the Department of Angiology and Vascular Surgery of the University Hospital of Vic, (Barcelona, Spain).

When is the study starting and how long is it expected to run for?
January 1997 to December 2012.

Who is funding the study?
1. Instituto de Salud Carlos III, Ministerio de Sanidad y Consumo (Spanish Ministry of Health) (Spain).
2. Non-Invasive Vascular Diagnosis Area of the Spanish Society for Angiology and Vascular and Endovascular Surgery (Sociedad Española de Angiología y Cirugía Vascular).

Who is the main contact?
Dr Josep Oriol Parés i Rifà

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
FIS 94/5365, FIS 97/0694

Study information

Scientific Title
Randomised controlled trial of surgical treatment of varicose veins in legs: Stripping versus Conservative Treatment (CHIVA)

Study objectives
Main Hypothesis:
The recurrence number of varicose veins to the saphenous vein system post-intervention by means of the CHIVA method is lower than the one used on Stripping regardless of the marking type system.

Secondary Hypotheses:
1. The recurrence number of varicose veins to the saphenous vein system post-intervention by means of Stripping with an Eco-Doppler mark method is lower than the one used on Stripping with a clinical mark method.
2. CHIVA method patients take fewer sick leave days than those ones treated with either of the others two methods.-
3. The CHIVA method cost is lower than the Stripping one regardless of the marking type system.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee for Clinical Research of the University Hospital of Vic, 21/07/2011, FIS 94 /5365, FIS 97/0694

Study design
Single-center interventional randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Varicose veins in legs

Interventions
Stripping with clinic marking, Stripping with Eco-Doppler marking, Conservative Treatment (CHIVA)

Intervention Type
Procedure/Surgery

Primary outcome measure
The clinic and haemodynamic determination of the recurrences number and the time between the intervention and recurrence will be calculated.

Secondary outcome measures
1. Time until medical discharge
2. Clinical and haemodynamic improvement
3. Satisfaction rate
4. Cost for each group

Overall study start date
01/01/1997

Completion date
31/12/2012

Eligibility

Key inclusion criteria
Patients affected by varicose veins of the lower extremities.

Added 23/11/2015:
The study included patients diagnosed with primary varicose veins in an external consultation by a vascular surgeon, according to the CEAP (CA-S, 2–6; EP; AS, P; PR; LII) classification criteria and with permeable, continent deep venous system upon duplex ultrasonography exploration. In patients with varicose veins in both extremities, only 1 limb could be randomized.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
501

Key exclusion criteria
Patients previously operated for varicose veins with recurrent varicose veins will be excluded.

Added 23/11/2015:
All patients with congenital venous disease, varicose veins secondary to prior deep vein thrombosis, postphlebitic side-effects, sclerotherapy, relapse of varicose veins after surgery, associated systemic pathologies, or who refused to participate in the study, refused surgical treatment, were not ambulatory, could not participate in long-term follow-up or had been pregnant less than 6 months previously were excluded from the study.

Date of first enrolment

01/02/1998

Date of final enrolment
01/04/2001

Locations

Countries of recruitment
Spain

Study participating centre
Hospital Universitari de Vic
C/ Francesc Pla el Vigata
Barcelona
Spain
08500

Sponsor information

Organisation
Spanish Ministry of Health, Investigation of Sanitary Funding (Fondo de Investigación Sanitaria Ministerio de Sanidad y Consumo)

Sponsor details
C/Sinesio Delgado, nº 6
Madrid
Spain
28029

Sponsor type
Government

Website
http://www.isciii.es/htdocs/index.jsp

ROR
https://ror.org/00f3x4340

Funder(s)

Funder type
Government

Funder Name
Investigation Sanitary Funding of Spanish Ministry of Health (Fondo de Investigación Sanitaria, Ministerio de Sanidad y Consumo) (Spain) (refs: 94/5365 and 97/0694)

Funder Name
Non-Invasive Vascular Diagnosis Chapter of Spanish Society of Angiology and Vascular Surgery (Capítulo de Diagnóstico Vascular no Invasivo de la Sociedad Española de Angiología y Cirugía Vascular) (Spain)

Results and Publications

Publication and dissemination plan
The study has been published in http://www.ncbi.nlm.nih.gov/pubmed/20224376. We are currently preparing the publication of the results at 10 years of follow up in 2016.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2010		Yes	No