

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 13/04/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 04/01/2016	Condition category Circulatory System	<input type="checkbox"/> 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

Contact name

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08500

Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

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

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