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

Submission date 05/03/2005	<b>Recruitment status</b> No longer recruiting	<ul><li>Prospectively registered</li><li>Protocol</li></ul>
<b>Registration date</b> 13/04/2005	<b>Overall study status</b> Completed	<ul> <li>[] Statistical analysis plan</li> <li>[X] Results</li> </ul>
Last Edited 04/01/2016	<b>Condition category</b> Circulatory System	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** Dr Josep Oriol Parés i Rifà

#### **Contact details**

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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