

Is the type of surgery in the groin influencing the coming back of varicose veins in the long term?

Submission date 19/01/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 01/02/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 01/02/2010	Condition category Circulatory System	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Wolfgang Mouton

Contact details
Krankenhausstrasse 12
Thun
Switzerland
3600

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Surgery as a trigger for neorevascularisation in recurrent saphenofemoral incompetence: a randomised trial of three different techniques

Study objectives

Surgery itself, and maybe the type of surgery, may trigger neorevascularisation in the groin when treating sapheno-femoral incompetence. The hypothesis is that one of the following three techniques is better - inducing less neorevascularisation - than the other two. If this would be the case this one technique should be preferred to the other two, worldwide.

The three techniques are:

1. Dissection under ligation
2. Dissection with electrocoagulation
3. Ultrasonic dissection

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Commission of the Regionalspital Thun approved on the 1st March 2002 (ref: 2:4;1.3)

Study design

Prospective randomised study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Prevention

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

Recurrent varicose veins

Interventions

The study was approved by the local Human Ethics Committee. All patients included in the study have informed pre-operative consent. 36 consecutive unselected patients underwent redo saphenous high ligation procedures during a period of thirteen months (1st April 2002 - 30th June 2003).

The study population comprised 34 female patients and 2 males. The age ranged from 24 to 73 years (mean 53 years). Thirty-two patients had undergone at least one previous procedure in the

groin. The patients were randomised to receive either dissection with ultrasound (Ultracision Harmonic Scalpel, Ethicon Endo-Surgery, Johnson and Johnson Company, Spreitenbach, Switzerland) or electrocoagulation (Elektrotom Berchtold GmbH&Co, Tuttlingen, Germany) or sharp dissection with ligation of scar and lymphatic tissue using absorbable suture material (Vicryl, Ethicon Endo-Surgery, Johnson and Johnson Company, Spreitenbach, Switzerland).

The groin was reopened via a transverse incision. The femoral artery was visualised as a landmark, after which the femoral vein was dissected and recurrent veins ligated and divided. Fascia and subcutaneous tissue was closed in two layers and included a vacuum wound drain. The skin was closed with sutures. Operating time is around one hour per procedure. The drain was removed one day post-operatively.

After three months a clinical and colour duplex ultrasonography investigation (Acuson Aspen, Acuson Corporation, Mountain View CA, USA) were carried out to detect lymphatic complications. After seven years a clinical and colour duplex ultrasonography investigation were carried out to detect and describe type and extent of neorevascularisation for the patients of all three treatment arms.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Clinical outcome and duplex sonography outcome at three months

VDS: venous disability score

VCSS: venous clinical severity score

Secondary outcome measures

Clinical outcome and duplex sonography outcome at seven years

VDS: venous disability score

VCSS: venous clinical severity score

Overall study start date

01/04/2002

Completion date

01/06/2010

Eligibility

Key inclusion criteria

1. Consecutive randomised patients with re-do surgery for sapheno-femoral incompetence in the groin
2. Written informed consent
3. Adults greater than 16 years old, either sex

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

36

Key exclusion criteria

Does not want to take part in the study

Date of first enrolment

01/04/2002

Date of final enrolment

01/06/2010

Locations**Countries of recruitment**

Switzerland

Study participating centre

Krankenhausstrasse 12

Thun

Switzerland

3600

Sponsor information**Organisation**

Regionalspital Thun (Switzerland)

Sponsor details

Krankenhausstrasse 12

Thun

Switzerland

3600

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/00m7t6760>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Regionalspital Thun (Switzerland) - paying incidental costs

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration