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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 01/02/2010	**Overall study status** Completed	
Last Edited 01/02/2010	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 neorevascularistion 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