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First operation in the groin to treat varicose veins: a comparison of two different surgical techniques with regards to reducing lymphatic complications

Submission date 01/07/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 11/07/2008	**Overall study status** Completed	
Last Edited 19/10/2009	**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
Primary surgery for saphenofemoral incompetence: a randomised controlled trial to compare two techniques to reduce lymphatic complications

Study objectives
The aim of this study was to prospectively compare two surgical techniques in primary high ligation such as sharp dissection with ligation of lymphatic tissue versus dissection with electrocoagulation in regard to the incidence of lymphocoele and lymphatic fistula. It is exspected that maybe sharp dissection with ligation of lymphatic tissue shows less lymphatic complications and would be therefore to be recommended.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Ethikkommission des Spital Thun STS AG (Switzerland) on the 1st December 2004 (ref: 3:16;27.9).

Study design
Prospective 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
Saphenofemoral incompetence

Interventions
Patients get operated on for symptomatic varicose vein disease classified C2 to C6 according clinical, aetiological, anatomical, pathological elements (CEAP). The CEAP classification is the common standard for classification of venous disorders and is widely used. All patients included in the study had informed preoperative consent. 134 consecutive unselected patients underwent bilateral primary saphenous high ligation procedures during a period of three and

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

The groin was opened via a transverse incision. The long saphenous vein up to the femoral vein was visualised, side branches ligated and the long saphenous vein flush-ligated with absorbable suture material. After the stripping of the long saphenous vein no wound drain was inserted and subcutaneous tissue was closed in one layer. The skin was closed with intracutaneous sutures. The wound was observed for lymphatic fistula and formation of a lymphocoele.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The wound was observed for lymphatic fistula and formation of a lymphocoele. After one and ten days a clinical investigation was carried out to detect lymphatic complications.

Secondary outcome measures
Further follow-up data were assessed by the means of the electronic patient record (EPR) (e.g., adverse events, complications, etc).

Statistical focus was on three parameters, all being defined in terms of a patient undergoing the two methods of operation:
p1 = probability of complications with method 1
p2 = probability of complications with method 2
p3 = probability of complications with just one of the two methods of operations

Differences were considered significant at an a level of 0.05, the software used was S-Plus Professional 6.2 (Insightful Corp., Seattle, USA).

Overall study start date
01/01/2005

Completion date
30/06/2008

Eligibility

Key inclusion criteria
1. Pre-operative written consent
2. Adults (greater than 16 years), either sex
3. The patient had to be operated on both areas of the groin

Participant type(s)
Patient

Age group

Adult

Sex
Both

Target number of participants
Initial target was at least 100 patients and therefore at least 200 procedures

Key exclusion criteria
Previously operated groin by arterial or venous operation.

Date of first enrolment
01/01/2005

Date of final enrolment
30/06/2008

Locations

Countries of recruitment
Switzerland

Study participating centre
Spital Thun STS AG
Thun
Switzerland
3600

Sponsor information

Organisation
Spital Thun STS AG (Switzerland)

Sponsor details
Department of Surgery
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Thun
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3600

Sponsor type
Hospital/treatment centre

Website
http://www.spitalstsag.ch

ROR
https://ror.org/00m7t6760

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (Switzerland)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2009		Yes	No