

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	<input type="checkbox"/> Prospectively registered
Registration date 11/07/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 19/10/2009	Condition category Circulatory System	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

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 lymphocele and lymphatic fistula. It is expected 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

Study type(s)

Treatment

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 lymphocele.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

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.

Key secondary outcome(s)

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).

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

ROR

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

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded (Switzerland)

Results and Publications

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