

Arm veins versus contralateral greater saphenous vein for lower extremity bypass reconstruction in patients with absent ipsilateral greater saphenous vein

Submission date 13/01/2014	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/02/2014	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 24/01/2019	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Patients suffering from peripheral arterial occlusive disease of the leg (narrowing of the arteries due to accumulation of fatty substances, such as cholesterol) need bypass surgery of the leg to avoid amputation. It is well known that the ipsilateral greater saphenous vein (the vein of the leg which has to be treated) is the best material for bypass reconstruction. In cases where the ipsilateral GSV is missing (due to a former bypass operation, vein stripping operation, trauma, etc), alternative bypass graft material has to be used, either autologous graft material (derived or transferred from the same person's body) or artificial graft material. Artificial graft materials have the disadvantage of significantly shorter patency rates (i.e., reduced likelihood that the vein will remain open), especially for below knee procedures, compared to autologous bypasses. Additionally, artificial grafts may have devastating effects for the patient in cases of graft infection. Autologous options in case of absent ipsilateral GSV are arm veins (basilic vein, cephalic vein), GSV of the contralateral (other) leg not undergoing bypass, or the lesser saphenous vein. The lesser saphenous vein (superficial vein of the calf) would be a reasonable alternative in case of absent ipsilateral GSV but is usually too short for below knee bypass reconstructions. Therefore, contralateral GSV and arm veins are the best bypass graft options for lower extremity revascularisation in case of absent ipsilateral GSV. The aim of this study is to assess the effectiveness and outcome of patients without ipsilateral GSV undergoing lower extremity bypass surgery using either arm veins (basilic vein and/or cephalic vein, Group A) or contralateral GSV (Group B).

Who can participate?

Men and women aged 30 years and older with peripheral arterial occlusive disease due to atherosclerosis.

What does the study involve?

Patients with absent ipsilateral GSV needing lower extremity bypass reconstruction are randomly allocated to Group A (arm vein bypass graft) or Group B (contralateral GSV bypass graft).

What are the possible benefits and risks of participating?

Patients taking part in the study will not directly benefit. Future patients will benefit because the study should show if the arm vein or the contralateral greater saphenous vein is the best choice.

Both procedures are performed routinely at our department. There are no special risks involved for the patients taking part in the study.

Where is the study run from?

Paracelsus Medical University (PMU), Salzburg, Austria.

When is the study starting and how long is it expected to run for?

The study started in June 2010 and will run until June 2016.

Who is funding the study?

Salzburg State Clinics (Salzburger Landeskliniken) (SALK) (Austria).

Who is the main contact?

Prof. Thomas Hölzenbein

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Arm veins versus contralateral greater saphenous vein for lower extremity bypass reconstruction in patients with absent ipsilateral greater saphenous vein: a randomized trial

Study objectives

Arm veins do better regarding bypass patency compared to contralateral greater saphenous vein (superficial vein of the contralateral leg) in patients needing lower extremity bypass surgery in case of absent ipsilateral greater saphenous vein (superficial vein of the leg which has to be treated).

The null hypothesis is that there will be no difference between arm veins and contralateral greater saphenous vein regarding bypass patency.

On 11/06/2014 the target number of participants was changed from 100 to 628.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Local Research Ethics Committee, PMU Salzburg, Austria, 30/10/2013, ref.: 415-E/1690/2-2013

Study design

Open randomized study

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

Peripheral arterial occlusive disease of the lower extremity

Interventions

Standard vein bypass techniques for lower limb revascularization in patients suffering from peripheral arterial occlusive disease.

For Group A patients arm veins (basilic and/or cephalic vein) are harvested and used as bypass graft
For Group B patients the contralateral greater saphenous vein is harvested and used for bypass reconstruction

Follow-up duration: 2 years

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Primary and secondary bypass patency measured at baseline, 1 month, 3 months , 6 months after discharge and then at 6-month intervals for 2 years

Secondary outcome measures

1. Local complications (e.g., surgical site infections)
2. Systemic complications (e.g., myocardial infarction, stroke)
3. Clinical and hemodynamic improvement
4. Limb salvage
5. Survival

Measured at baseline, 1 month, 3 months , 6 months after discharge and then at 6-month intervals for 2 years.

Overall study start date

01/06/2010

Completion date

01/06/2016

Reason abandoned (if study stopped)

Technical reasons

Eligibility

Key inclusion criteria

1. Male or female aged 30 years and over
2. Claudication > 2 months
3. Critical leg ischemia > 2 months
4. Popliteal aneurysm
5. Absent ipsilateral greater saphenous vein
6. Usable arm vein (cephalic and/or basilic vein without signs of sclerosis or thrombosis and with diameter > 2.5 mm verified by preoperative duplex)
7. Usable contralateral greater saphenous vein (without signs of sclerosis or thrombosis and with diameter > 2.5 mm verified by preoperative duplex)
8. Atherosclerosis

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

628

Key exclusion criteria

1. Urgent critical leg ischemia (thromboembolic event < 2 months)
2. Absent arm vein (e.g., due to prior operation)
3. Unusable arm vein (due to sclerosis and/or thrombosis and/or small (< 2.5 mm) diameter verified by preoperative duplex)
4. Absent contralateral greater saphenous vein (due to prior coronary bypass, peripheral bypass, vein stripping, trauma, etc)
5. Unusable contralateral greater saphenous vein (due to sclerosis and/or thrombosis and/or small (< 2.5 mm) diameter verified by duplex)
6. Arm veins should be saved for arterio-venous fistula
7. Deep vein thrombosis of the contralateral leg
8. Critical leg ischemia of the contralateral leg
9. Trauma

Date of first enrolment

01/06/2010

Date of final enrolment

01/06/2016

Locations

Countries of recruitment

Austria

Study participating centre

Müllner Hauptstrasse 48

Salzburg

Austria

5020

Sponsor information

Organisation

Paracelsus Medical University (PMU) (Austria)

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Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/03z3mg085>

Funder(s)

Funder type

Government

Funder Name

Salzburg State Clinics (Salzburger Landeskliniken) (SALK) (Austria)

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