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# 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

**Registration date**
12/02/2014

**Overall study status**
Stopped

**Last Edited**
24/01/2019

**Condition category**
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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
Prof Thomas Hölzenbein

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# Additional identifiers

### Protocol serial number
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

## Study type(s)
Treatment

## 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(s)

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

### Key secondary outcome(s))
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.

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
All

### 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)

### ROR
https://ror.org/03z3mg085

## Funder(s)

### Funder type
Government

### Funder Name
Salzburg State Clinics (Salzburger Landeskliniken) (SALK) (Austria)

# 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? |
|---|---|---|---|---|---|
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |