“Tissue damage due to harvesting of the Great Saphenous Vein (GSV) for femoropopliteal bypass surgery”

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22486

Source
Nationaal Trial Register

Health condition

Peripheral arterial disease (PAD) requiring bypass surgery for adequate blood supply to the distal leg/foot, with autologous material (GSV).

Sponsors and support

Primary sponsor: Zuyderland Medical Center, Heerlen
Source(s) of monetary or material Support: Zuyderland Medical Center, Heerlen

Intervention

Outcome measures

Primary outcome

Tension of GSV in millinewton (mN), contraction time in minutes, relaxation time in minutes, percentage of relaxation. Endothelial expression.

Secondary outcome

-

Study description

Background summary

Patients with symptomatic PAD often require surgical interventions when experiencing ischemic rest pain, tissue loss or ulceration of the leg/foot (Rutherford 4-6). When endovascular interventions are not an option, open procedures such a bypass surgery might function as a last resort. Preferably autologous material is used for creating bypass grafts. The Greater Saphenous Vein (GSV) is the vein of first choice. To harvest the GSV three techniques are generally used, namely;
Standard reversed technique using additional incisions in the trajectory of the GSV, Reversed technique with a minimal invasive harvesting technique, and the in situ technique with the use of valvulotomy. To determine the quality of the harvested vein after being subtracted by either one of three harvesting techniques. We will subject the remainder (wasted section) of the harvest veins to vasomotor tests and evaluate the quality of the endothelial tissue (after staining) using an electron microscope. We sought to determine the best possible and minimally invasive
technique of subtracting the GSV while maintaining optimal function and tissue quality of the GSV to be used as a bypass graft.

Study objective

To use the GSV for bypass surgery it is of the utmost importance to subtract the vein with as limited damage as possible. To harvest the GSV three techniques are generally used, namely; Standard reversed technique using additional incisions in the trajectory of the GSV, Reversed technique with a minimal invasive harvesting technique, and the in situ technique with the use of valvulotomy. We hypothesise that harvesting the GSV with the use of minimally invasive harvesting technique to be less (or equally) traumatic to the venous tissue, while retaining optimal function, when compared to the traditional techniques.

Study design

<72 hours after harvesting.

Intervention

18 patients will be included in this study. Three separate arms with each six harvested veins are required. The veins in each separate group are harvested with one of the previously mentioned techniques. The rest over section of the harvested GSV will be used for examination under an electron microscope after immunohistochemical staining of the endothelial cells with CD-31 and CD-34. Functional tests will be performed with a myograph to test the vasomotor function of the GSV after exposure to calcium/chloride,

acetylcholine and nitroprusside.

Contacts

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Eligibility criteria

Inclusion criteria

- Patients requiring supragenual or infragenual bypass surgery for sufficient blood supply to the distal leg.

- A circumference of >3mm of the GSV of the affected leg.

- Harvesting the GSV for bypass surgery often leaves an unused section of approximately five centimetres. This left over section is often discarded as waste. No additional harm or surgery is needed.

- Informed consent

Exclusion criteria

- GSV <3mm

- Previous intervention involving the GSV

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2015
Enrollment:	18
Type:	Anticipated

Ethics review

Positive opinion

Date:	06-07-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5152
NTR-old	NTR5292

Register	ID
Other	15-N-100 : METC Atrium-Orbis-Zuyd

Study results