

PILOTSTUDY MEASUREMENTS OF LOWER LEG VOLUME BY CT SCAN

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In this pilotstudy we will investigate if it is feasible to measure volume increase in a operated leg by means of a CT scan

Ethical review	Approved WMO
Status	Pending
Health condition type	Arteriosclerosis, stenosis, vascular insufficiency and necrosis
Study type	Observational non invasive

Summary

ID

NL-OMON31416

Source

ToetsingOnline

Brief title

leg volume and ct scan

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym

leg edema

Research involving

Human

Sponsors and support

Primary sponsor: Onze Lieve Vrouwe Gasthuis

Source(s) of monetary or material Support: OLVG

Intervention

Keyword: ct scan, leg, volume

Outcome measures

Primary outcome

volume measurement/increase of de operated leg

Secondary outcome

VAS score

volumedifference with the other leg

Study description

Background summary

After peripheral vascular bypass surgery many patients suffer postoperative leg swelling. There are no objective methods to measure this swelling. In future we want to test medication to prevent this swelling. Therefore we need to develop a tool to objectivate this swelling

Study objective

In this pilotstudy we will investigate if it is feasible to measure volume increase in a operated leg by means of a CT scan

Study design

included are patients with peripheral bypass surgery. 1 day before operation and 1 week after a CT scan will be made of both legs.

Study burden and risks

no burden

minimal/no risk (background radiation comparable with 1 year living in Holland)

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- patients for peripheral bypass surgery: supra- and infragenual

Exclusion criteria

- woundinfection

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL
Recruitment status: Pending
Start date (anticipated): 01-03-2007
Enrollment: 10
Type: Anticipated

Ethics review

Approved WMO
Application type: First submission
Review commission: MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
CCMO	NL16574.067.07