

# Quality of life in patients with peripheral arterial disease: the Vascular Quality of Life-6 Questionnaire (VascuQoL-6) study

|                                        |                                                   |                                                                                                   |
|----------------------------------------|---------------------------------------------------|---------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>29/05/2017   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>31/05/2017 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>26/08/2020       | <b>Condition category</b><br>Circulatory System   | <input type="checkbox"/> Individual participant data                                              |

## Plain English summary of protocol

### Background and study aims

Peripheral arterial disease (PAD) is a common condition where a build-up of fatty deposits in the arteries (blood vessels) restricts the blood supply to the leg muscles. The aim of this study is to test the Vascular Quality of Life-6 Questionnaire (VascuQoL-6) for assessing the quality of life of patients with peripheral arterial disease.

### Who can participate?

Patients of any age with pain during walking, pain when at rest, or ulcers on their feet or legs

### What does the study involve?

All participants complete the VascuQoL-6 questionnaire and their scores are compared to the scores from a longer form, as well as to measurements of the blood flow to the legs and to their walking capacity measured on a treadmill. Regardless of the treatment they receive, all participants are scheduled for two follow up appointments to repeat all of the measurements after 4 weeks and after 1 year.

### What are the possible benefits and risks of participating?

The results from the study will indicate whether this questionnaire can be used for all patients. Participation in the study does not alter the treatment of the patient's condition, and there is no risk involved.

### Where is the study run from?

1. Sykehuset Østfold HF (Ostfold Hospital Trust) (Norway)
2. Akershus Universitetssykehus HF (Akershus University Hospital) (Norway)

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

January 2014 to January 2017

Who is funding the study?

1. Sykehuset Østfold HF (Ostfold Hospital Trust) (Norway)
2. Akershus Universitetssykehus HF (Akershus University Hospital) (Norway)

Who is the main contact?

1. Dr Anne Sofie Larsen (public)
2. Dr Jarlis Wesche

## Contact information

### Type(s)

Public

### Contact name

Dr Anne Sofie Larsen

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### Contact details

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### Type(s)

Scientific

### Contact name

Dr Jarlis Wesche

### Contact details

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1478

## Additional identifiers

### Protocol serial number

REK 2014/221

## Study information

### Scientific Title

Validation of the Vascular Quality of Life-6 Questionnaire (VascuQoL-6) for use in patients with peripheral arterial disease

**Acronym**

VascuQoL-6

**Study objectives**

Patient reported outcome (PROM) is very important in patients suffering from peripheral arterial disease (PAD), as the current available outcome measures of systolic arterial pressure measurements and walking capacity do not reflect the patient experience after treatment, especially for patients suffering from the milder forms of the disease (intermittent claudication). VascuQoL-6 is designed as a PROM intended for vascular procedural registries and clinical practice, but has not yet been validated. The aim of the study is to evaluate how VascuQoL-6 performs as a disease-specific Quality of Life instrument in a unselected patient population with PAD in secondary health care.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Regional Committees of Medical and Health Research Ethics (in Norway), South East Office, date of approval 25/03/2014, minor alteration 11/05/2015, ref: REK 2014/221

**Study design**

Observational longitudinal study

**Primary study design**

Observational

**Study type(s)**

Quality of life

**Health condition(s) or problem(s) studied**

Peripheral arterial disease (PAD)

**Interventions**

Observational longitudinal cohort from two secondary health care centres with observation at inclusion, after 4 weeks and 1 year. Validation of the VascuQoL-6 questionnaire is done by an anchor-based approach. The patients complete the generic health status instrument SF-36 and VascuQoL-6 prior to each consultation. Data from the vascular laboratory (systolic arterial pressure measurements and treadmill performance) and from the clinical consultation by the vascular surgeon are used as anchors. Correlation analysis and internal consistency are calculated from baseline data. Reliability is evaluated after 4 weeks in patients without invasive treatment, and responsiveness to change is evaluated in patients who receive invasive treatment.

**Intervention Type**

Other

**Primary outcome(s)**

Vascular quality of life, measured using the VascuQoL-6 summary score at baseline and after 4 weeks and 1 year

**Key secondary outcome(s)**

1. Generic health status, measured using SF-36
2. Ankle-brachial index (ABI), measured using handheld Doppler and circular cuff at the ankle at rest and after exercise
3. Walking capacity, measured on a treadmill (2.5 km/h, 0 degrees of incline) for a maximum of 10 minutes
4. Peripheral artery disease clinical evaluation, using the Rutherford/Fontaine clinical classification systems

Measured at baseline and after 4 weeks and 1 year

**Completion date**

01/01/2017

## Eligibility

**Key inclusion criteria**

1. Patients referred to the department of vascular surgery at the participating hospitals for evaluation of potential or established peripheral arterial disease, regardless of age or gender
2. Eligibility is decided by the vascular surgeon evaluating the referral documents from physicians in primary health care. Information about the study and invitation to participate will be issued with the appointment details
3. Consecutive inclusion of patients with exclusion if the diagnostic work up do not indicate peripheral arterial disease

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Total final enrolment**

171

**Key exclusion criteria**

Patients not suffering from peripheral arterial disease as primary explanation of symptoms (differential diagnosis)

**Date of first enrolment**

01/08/2014

**Date of final enrolment**

01/01/2016

## Locations

## Countries of recruitment

Norway

## Study participating centre

**Akerhus Universitetssykehus HF**

Postbox 1000

Lørenskog

Norway

1478

## Study participating centre

**Sykehuset Østfold HF**

Grålum

Norway

1714

# Sponsor information

## Organisation

Sykehuset Østfold HF

## ROR

<https://ror.org/04wpcxa25>

# Funder(s)

## Funder type

Hospital/treatment centre

## Funder Name

Sykehuset Østfold HF (Ostfold Hospital Trust)

## Funder Name

Akershus Universitetssykehus HF (Akershus University Hospital)

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Anne Sofie Larsen.

## IPD sharing plan summary

Available on request

### Study outputs

| Output type                     | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 22/09/2017   | 13/07/2020 | Yes            | No              |
| <a href="#">Results article</a> | results | 17/07/2020   | 26/08/2020 | Yes            | No              |