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

Submission date
29/05/2017

Recruitment status
No longer recruiting

Registration date
31/05/2017

Overall study status
Completed

Last Edited
26/08/2020

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Longitudinal study

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
The patient participation information is in Norwegian, please use the contact details to request a patient information sheet

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

Secondary outcome measures
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

Overall study start date
01/01/2014

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

Age group
Adult

Sex
Both

Target number of participants
200

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
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1714

Sponsor information

Organisation
Sykehuset Østfold HF

Sponsor details
Postboks 300
Grålum
Norway

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forskningsavdelingen@so-hf.no

Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan
Publication of the results in a peer-reviewed open access journal.

Intention to publish date
31/12/2018

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?
Results article	results	22/09/2017	13/07/2020	Yes	No
Results article	results	17/07/2020	26/08/2020	Yes	No