Venous claudication treadmill trial

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Ethical review	Approved WMO
Status	Completed
Health condition type	Embolism and thrombosis
Study type	Observational non invasive

Summary

ID

NL-OMON55978

Source ToetsingOnline

Brief title VCT-trial

Condition

• Embolism and thrombosis

Synonym Venous insufficiency. Venous claudication

Research involving Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam **Source(s) of monetary or material Support:** Ministerie van OC&W

Intervention

Keyword: Endovascular stenting, Post-thrombotic syndrome, Treadmill test, Venous claudication

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Outcome measures

Primary outcome

o Distance in meters on a standardized treadmill test until patients develop known symptoms as tightness and/or pain: initial claudication distance (ICD). o Distance in meters on a standardized treadmill test until patients develop severe known symptoms as tightness and/or pain that compel them to stop walking: absolute claudication distance (ACD).

o Time in minutes on a standardized treadmill test until patients develop known symptoms as tightness and/or pain: initial claudication time (ACT).

o Time in minutes on a standardized treadmill test until patients develop

severe known symptoms as tightness and/or pain that compel them to stop

walking: absolute claudication time (ACT).

Secondary outcome

- o Quality of life using the VEINES-QoL questionnaire
- o Symptom severity using the VEINES-Sym questionnaire
- o PTS score using the Villalta score
- o VAS score
- o Leg circumference in centimetres using a measuring tape

Study description

Background summary

Venous claudication (VC) is the feeling of tightness of the thigh or leg caused by an obstruction in the venous system of various etiologies. Usually it is one of many long-term consequences after deep vein thrombosis (DVT) of the lower extremities. Post-thrombotic changes in the deep venous system can restrict

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blood flow back to the heart. As a result, patients may experience leg and thigh cramping and even pain, among other things. This is called venous claudication. Symptoms usually resolve within 20 minutes of rest or after lifting the leg.

Venous claudication is part of many venous symptoms and signs that can occur after a DVT, often described as postthrombotic syndrome (PTS). In practice, diagnosing PTS is done using scoring systems, such as the Villalta score, Venous Clinical Severity Score (VCSS), or CEAP classification. These consist of questions about patients' symptoms and criteria that can be observed on physical examination. However, venous claudication is not an item in any of these assessment tools, and to date none of the above classification systems have been validated to measure PTS. In research, single venous symptoms and signs are often measured as a derivative of the severity of PTS, such as leg circumference, tingling, and pain. There is hardly any literature on methods to objectively diagnose and assess VC, instead patients often state their symptoms of cramping and pain experienced during exercise. For many patients, severe VC is a serious disability leading to a significantly reduced quality of life and significant socio-economic costs.

Patients who choose treatment are referred to a dermatologist or vascular surgeon, who evaluates the degree of PTS and the presence, type, location, and extent of venous obstruction. While there is currently no objective method to diagnose and score the severity of venous claudication or PTS, invasive treatment may be considered in patients with severe symptoms. In these patients, a stent is placed to reconstruct the blocked arteries. The goal is to establish adequate drainage of blood from the leg through the recanalized segment. That reduces venous pressure and volume, which in turn should improve symptoms. The success of this procedure is often judged by the patency of the stents and the improvement in the patient's symptoms and quality of life. Up to 83% of patients report an improvement in VC after stent placement.

On the other hand, there is an overwhelming amount of data on treadmill testing for assessing the severity of claudication caused by obstruction in the arterial system. This treadmill test is fully standardized and can be used both to diagnose arterial claudication and to assess the effect of treatment. For venous claudication, this test is not used in current practice and only a few studies have assessed the prevalence of PTS and VC using a treadmill test. Only one study assessed whether placing a postthrombotic iliofemoral obstruction reduced venous hypertension while using treadmill stress testing in combination with invasive pressure measurements.

Study objective

The goal of our study is to evaluate if it is feasible to incorporate a standardized treadmill test into the workup of a patient with an iliofemoral venous obstruction, who is planned for venous stenting, before and after the

procedure. We want to investigate if we are able to record the occurrence of VC during the test as well as changes in distance and time without symptoms, after stent placement. We will add leg circumference, PTS, VAS and QOL questionnaires, as these are standard of care in our centre. We intend to perform a larger study depending on the outcomes of this pilot study. Results can be used for a better understanding of VC in relation to symptom severity, to hopefully quantify the degree of VC, and to objectively measure the effect of endovascular stenting.

Study design

This will be a single center pilot study as there is little literature on the feasibility of treadmill testing to assess venous claudication. We also plan to conduct a larger study, depending on the results of this pilot study. We expect the total duration of the study to be 6 months, including inclusion and testing before and after the intervention.

Intervention

Patients will perform a treadmill exercise test. The treadmill test is standardized and will have pre-set of the speed (3.2km/h) and inclination of 0% at the beginning according to the protocol based on the study of Kurstjens et al. Each 2 minutes, the inclination is increased by 2%. Participants are asked to walk on a treadmill until they experience recognizable symptoms in their affected leg such as tightness, pain, fatigue, heaviness, cramps or stiffness.

Study burden and risks

The only disadvantageof during study is that we will continue with the treadmill test until participants develop complaints that may affect them. However, if serious complaints occur, we will stop the test. In addition, these symptoms are no different from those they may already experience during their normal physical activity. In addition, we expect that patients will come to Erasmus MC twice for the examination for an estimated time of 1.5 hours per visit.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age Adults (18-64 years)

Inclusion criteria

- Voluntary and mentally competent individuals from 18 years of age
- Understanding of the Dutch language
- Symptoms of venous claudication after a prior DVT with an indication for endovascular stenting.
- Able to perform a treadmill exercise test.
- Written informed consent

Exclusion criteria

- Having any other morbidity that prevent patients from performing a walking test.

- Having any other morbidity that mimics similar symptoms, most of all arterial claudication

- Inability to give informed consent (cognitive impairments, no good understanding of the Dutch language)
- Prior vascular intervention for an acute DVT (surgery, interventional catheter-directed thrombolytic therapy, stent)
- Participating in other research projects that can influence outcomes of this study (such as venous interventions, physical exercise programs)
- Pregnancy up to 2 months postpartum

Study design

Design

Study type: Observational non invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Diagnostic	

Recruitment

NL	
Recruitment status:	Completed
Start date (anticipated):	07-09-2023
Enrollment:	5
Туре:	Actual

Ethics review

Approved WMO	
Date:	11-08-2023
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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

ССМО

ID NL84143.078.23