Evaluation of popliteal artery entrapment in healthy individuals

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To investigate in healthy individuals not having ELP whether DUS and dynamic MRI may reveal a compressed popliteal artery in rest and during provocative testing (pointing, plantar foot flexion).

Ethical review	Approved WMO
Status	Pending
Health condition type	Vascular injuries
Study type	Observational non invasive

Summary

ID

NL-OMON57179

Source
ToetsingOnline

Brief title
Popliteal artery entrapment in healthy individuals

Condition

- Vascular injuries

Synonym
'Popliteal artery entrapment' 'Entrapment of the knee artery'

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum
Source(s) of monetary or material Support: Gecombineerd;door: Stichting Stimuleren Sportgeneeskunde ZOB. Daarnaast zal een aanvraag worden ingediend bij het COI.

Intervention

Keyword: Doppler Ultrasonography, Healthy Volunteers, Magnetic Resonance Imaging, Popliteal artery

Outcome measures

Primary outcome

To determine the rate of popliteal artery compression during DUS and dynamic

MRI in a group of healthy asymptomatic individuals.

Secondary outcome

n.v.t.

Study description

Background summary

Popliteal artery entrapment syndrome (PAES) is an uncommon lower leg pain syndrome predominantly affecting young athletes. It refers to a condition in which the popliteal artery is compressed by calf muscles and is classified as one of the vascular causes of *exercise-induced lower leg pain syndromes* (ELP). PAES patients most often suffer from the functional type (fPAES), where too bulky well-developed muscles compress the popliteal artery. In contrast, a small portion of patients have symptoms due to an abnormal position of the artery relative to the muscles leading to vascular compression (anatomical PAES).
Due to a reduction in arterial perfusion and lack of oxygen, individuals with symptomatic PAES often experience calf cramping, pain, muscle weakness and tingling sensations during exertion. The pattern of these symptoms may resemble other types of ELP such as the deep posterior type of chronic exertional compartment syndrome (dp-CECS). During dp-CECS, symptoms are thought to occur from elevated muscle pressures that can be measured using an invasive pressure analysis.
Discrimination between PAES and dp-CECS may be exceedingly difficult. As both PAES and CECS are relatively unknown syndromes, rates of underdiagnosis and protracted diagnostic delay are high. It is important that patients are correctly diagnosed in order to institute the best treatment. There is a direct relation between diagnostic delay and treatment outcome. Moreover, untoward events such as irreversible damage to the arterial wall in PAES with subsequent acute occlusion must be prevented at all times. Therefore, the diagnostic

regimen should be optimized.
If PAES is suspected by a patient history while the compartment pressure is inconclusive, duplex ultrasonography (DUS) during lower leg provocative tests (pointing, active plantar flexion) is indicated. In addition, a walking test with Ankle-Brachial Index (ABI) measurement after a provocative exercise is performed, allowing for observation of the patient. Dynamic magnetic resonance imaging (MRI) during provocation may help to distinguish between a case of anatomical and functional PAES.
There is a strong need for identification of a diagnostic gold standard for fPAES. However, earlier DUS studies have demonstrated that compression of the popliteal artery is quite common in healthy individuals not having any lower leg symptoms (up to 50%!). Whether these healthy asymptomatic individuals with abnormal DUS images may also show popliteal artery compression during a dynamic MRI is unknown.

Study objective

To investigate in healthy individuals not having ELP whether DUS and dynamic MRI may reveal a compressed popliteal artery in rest and during provocative testing (pointing, plantar foot flexion).

Study design

Descriptive study with exploratory elements in which healthy volunteers undergo a DUS and a dynamic MRI. A walking test with Ankle-Brachial Index (ABI) is performed to rule out other causes of ELP. There is one study arm, no comparator and no randomisation.

Study burden and risks

Individuals will complete a 10 minute symptom questionnaire and a questionnaire to ensure safety of the MRI-scan. They will walk for 5 minutes on a treadmill while being observed by a vascular technician. They will then undergo a 15-minute ultrasound analysis of both popliteal fossae in prone position. The MRI analysis will last 45-60 minutes.
There is no harm associated with a DUS or walking test. Provided a volunteer does not have implants and is not claustrophobic, an MRI is not harmful. All tests will be planned during one day, ideally within a 2-hour time frame. Subjects will receive ¤50 for a complete participation. Other than that, they will not benefit from this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

>=18 years, <30 years
Proficient in speaking and reading Dutch
Healthy and mentally competent

Exclusion criteria

Presence of complaints suggesting an exercise-induced lower leg pain syndrome or previously diagnosed with an ELP;
History of recent (1 year) surgery or trauma in the lower legs;
Limb pathologies or anomalies such as:
o Peripheral arterial or venous disease
o Muscle disorders
o Diabetes mellitus
o Peripheral neuropathy
Unable to point or flex the foot;
Lower leg wounds.

Osteosynthesis material in the legs.
Implants.
Smoking.

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):	01-06-2024
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

Date:	24-09-2024
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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	NL86404.015.24