Diagnostic accuracy of the maximal systolic acceleration for detection of peripheral arterial disease in patients with diabetes-related foot ulceration.

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The aim of this study is to assess the clinical value of bedside tests compared to DUS to detect PAD in patients with diabetes-related foot ulceration, with special emphasis on the ACCmax.

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

Summary

ID

NL-OMON51397

Source
ToetsingOnline

Brief title
DIAMACC study (DIAbetes Maximal ACCeleration)

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Peripheral arterial disease, vascular disease

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: ACCmax, Diabetes Mellitus, Diagnostics, Peripheral Arterial Disease

Outcome measures

Primary outcome

Sensitivity and specificity including their derivates PLR and NLR in the diagnostic accuracy of the ACCmax for peripheral arterial disease in the diabetic foot.

Secondary outcome

* Correlation patient demographics and comorbidities with diagnostic accuracy

* Comparison of ACCmax with sensitivity/specificity of current bedside tests

* Collecting follow-up data for prognostic patient group evaluation, such as wound healing, revascularisation probability, complications and mortality.

Study description

Background summary

According to the latest 2021 data from the International Diabetes Federation, an estimated 537 million adults are living with DM globally. Prevalence is increasing rapidly, with numbers projected to rise to 643 million by 2030 and 783 million by 2045. Annually, DM causes 6.7 million deaths, as a consequence of both macrovascular- (atherosclerosis) and microvascular disease (retinopathy, nephropathy, and neuropathy).

Peripheral arterial disease (PAD) of the lower extremity is a clinical manifestation of systemic atherosclerosis and considered a well-known (long-term) complication of DM. Besides atherosclerosis, calcification of the tunica media of the arterial wall can occur. This process is called medial arterial calcification (MAC) and is accelerated in the presence of DM. Research suggests that MAC is present in approximately one third of patients with DM. MAC has been shown to be an independent predictor of cardiovascular mortality,

while another study found that patients with DM and PAD have an impaired quality of life and an increased risk of adverse cardiac and limb events.

Timely recognition of limb ischemia is important in patients with DM/MAC in order to reduce delayed wound healing, prevent lower limb amputation and eventually reduce mortality. Current non-invasive bedside tests - such as the ankle-brachial index (ABI) and toe pressure (TP) - are considered accurate for the diagnosis of PAD. However, as shown in previous systematic reviews, the performance of current bedside tests is not reliable in excluding PAD in diabetic patients. The methodological quality of the studies in these reviews were poor. In general, most of the data was collected retrospectively and not all patients received reference testing. In order to assess the reliability of bedside tests in this patient group, more well-sound methodological research is required. Also alternative bedside tests need to be investigated.

The doppler derived maximal systolic acceleration (ACCmax) is a new non-invasive parameter, which could be promising in detecting PAD. Although ACCmax has already been used for renal artery stenosis, thorough evaluation has not been performed in PAD. Two previous studies showed accurate diagnostic property in diabetic patients, but the sample sizes were small.

Study objective

The aim of this study is to assess the clinical value of bedside tests compared to DUS to detect PAD in patients with diabetes-related foot ulceration, with special emphasis on the ACCmax.

Study design

Comparative diagnostic accuracy study, prospectively enrolled.

Study burden and risks

- More elaborate diagnostic tests during first visit (approximately 30 minutes more)
- No burden or risks, since all tests are non-invasive and are harmless

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- 18 years or older.
- Diabetes Mellitus in medical history.
- Presenting with a diabetic foot ulcer with initiation of a new diagnostic carepath

Exclusion criteria

Lacking capacity to consent to inclusion.

Study design

Design

Study type: Observational non invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	27-11-2023
Enrollment:	198
Type:	Actual

Ethics review

Approved WMO

Date:	24-03-2023
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	15-10-2024
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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
ClinicalTrials.gov	NCT05646147
CCMO	NL80875.058.22