

Validation study to assess limitations in mobility among patients with type 2 diabetes.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Diabetic complications
Study type	Observational non invasive

Summary

ID

NL-OMON31102

Source

ToetsingOnline

Brief title

Validationstudy limitations in mobility among patients with diabetes.

Condition

- Diabetic complications

Synonym

insulin-independent diabetes mellitus, type 2 diabetes

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Ziekenhuis Maastricht

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

Intervention

Keyword: measuring mobility, type 2 diabetes mellitus, validationstudy

Outcome measures

Primary outcome

Correlation between the 6 minutes walk and the time to get up and go, balance tests and walking an 8 stairway up and down.

Secondary outcome

Prevalence of limitations in mobility, measured with the 6 minutes walk, and the difference in prevalence between patients without polyneuropathy and peripheral arterial disease, patients with polyneuropathy and patients with both polyneuropathy and peripheral arterial disease.

Study description

Background summary

Limitations in mobility are an important and common problem among people with type 2 diabetes. It is important to reduce limitations in mobility among people with diabetes. Interventions are effective in increasing the physical activity and reducing mobility limitations. However, it is unknown which people have to be selected for an intervention. In order to make a good selection, valid measurements of limitations in mobility should become available.

Study objective

The primary goal is to examine which measurements of limitations in mobility are valid among people with type 2 diabetes in primary health care. The study also contributes to the knowledge of the prevalence of limitations in mobility among people with diabetes in primary care.

Study design

Cross-sectional observation study.

Study burden and risks

People included in the study will not run more risk compared to daily life.
People will undergo one measurement and no invasive measurements are being used.

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

Type 2 diabetes mellitus, age > 40 years and able to walk at least 6 minutes unassisted

Exclusion criteria

limited mobility due to severe joint problems, any amputation exceeding toe amputation(s), foot ulcer < 1 year ago, severe peripheral arterial disease (claudication with walking distance less than 1000 meter and/or Doppler ankle brachial index less than 0.7), myopathies, CVA with motor impairment, cancer, severe exercise capacity limitations (NYHA classification > 2) due to cardiac or pulmonary disfunction (decompensatio cordis, angina pectoris, recent myocardial infarction (< 6 months)), pregnancy, high intake of alcohol and drugs, weight change more than 4 kg in the last 4 weeks, severe rheumatoid arthritis, knee- or ankleprosthesis, vision < 0.5 with correction

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 29-10-2007

Enrollment: 102

Type: Actual

Ethics review

Approved WMO

Date: 12-09-2007

Application type: First submission

Review commission: METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL18781.068.07