

Diabetes and walking exercise

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

Summary

ID

NL-OMON37646

Source

ToetsingOnline

Brief title

Diabetes and walking exercise

Condition

- Diabetic complications
- Electrolyte and fluid balance conditions

Synonym

diabetes

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud

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

Intervention

Keyword: Exercise, Fluid balance, Type 1 Diabetes Mellitus, Type 2 Diabetes Mellitus

Outcome measures

Primary outcome

- Fluid balance (by means of body mass loss)

Secondary outcome

- Incidence of dehydration
- Urine output
- Fluid intake
- Electrolyte balance
- Heart rate
- Activity level
- Glucose homeostasis

Study description

Background summary

Type 2 Diabetes Mellitus (T2DM) represents a major health problem in the Western society. Physical inactivity plays a detrimental role in the development of T2DM, but also contributes to the increased cardiovascular risk.

To support this notion, exercise training has various beneficial effects, including improvement in insulin sensitivity and cardiovascular risk factors.

Walking exercise represents an attractive type of exercise that can be performed everywhere. However, relatively little is known about the immediate effect of walking exercise training in T2DM.

When walking exercise is performed for prolonged periods, such as during the Nijmegen 4-Day marches, subjects may develop a fluid- or electrolyte imbalance.

In a series of previous experiments, we found that fluid- and electrolyte imbalance occurs more often in men, older subjects and subjects with overweight/obesity. Because of these risk factors, T2DM patients may be at risk for developing fluid- and electrolyte imbalance compared to healthy controls.

Moreover, relatively little is known about the impact of prolonged walking exercise on glucose levels, which may be importantly influenced by this type of exercise. We also want to include a group of Type 1 Diabetes Mellitus (T1DM) patients. Similar to T2DM, exercise training has potent cardioprotective

effects, whilst relatively little is known about the acute effects of exercise. Whether T1DM is associated with fluid- and electrolyte imbalance is currently unknown.

Study objective

The primary aim of this study is to assess the impact of prolonged walking on fluid- and electrolyte balance in 32 patients with T2DM, compared with a matched group of 32 healthy control subjects, and 32 patients with T1DM, during the Nijmegen Four Day Marches. As a secondary aim, we will examine glucose homeostasis during prolonged walking exercise in a subgroup of T2DM, T1DM and controls.

Study design

Observational study

Study burden and risks

During the 4-day marches, we will take daily venous blood samples and perform non-invasive measurements to gain better insight into the hydration status of subjects (such as body weight changes after exercise). In addition, continuous glucose monitoring will be applied to measure glucose homeostasis as a pilot study in a subgroup of 10 T2DM patients, 10 healthy control subjects, and 10 T1DM patients. For organization purposes, this will be performed a few weeks before the 4-day marches. All measures, therefore, are minimally invasive and not associated with an important health risk for these patients, and will provide important and novel information about the impact of walking exercise in patients and controls.

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

- Diagnosed with T2DM
- Diagnosed with T1DM

Exclusion criteria

- Body weight lower than 36,5 kg
- Presence of an obstructive disease of the gastro-intestinal tract, including (but not only) diverticulosis and inflammatory intestinal disease.
- History of surgery of the intestines, excluding cholecystectomy and appendectomy
- Magnetic Resonance Imaging (MRI) planned during the period in which subjects have ingested the CorTemp™ sensor or planned 48 h after the 4-Day Marches.
- pacemaker or presence of another electromedical apparatus; Besides these exclusion criteria we will not adhere to any other exclusion criteria. This is to ensure that our research population is as much akin to the general four days marching population as possible.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial

Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2012
Enrollment:	96
Type:	Actual

Ethics review

Approved WMO	
Date:	28-06-2012
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	15-11-2013
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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

CCMO

ID

NL40431.091.12