

Research protocols Kilimanjaro Challenge, 10-26 October 2008

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Observational non invasive

Summary

ID

NL-OMON32833

Source

ToetsingOnline

Brief title

Research protocols Kilimanjaro Challenge

Condition

- Cardiac disorders, signs and symptoms NEC
- Glucose metabolism disorders (incl diabetes mellitus)

Synonym

diabetes, type 1 diabetes mellitus

Research involving

Human

Sponsors and support

Primary sponsor: Stichting Medisch Researchfonds Zwolle

Source(s) of monetary or material Support: Stichting Researchfonds inwendige geneeskunde Zwolle

Intervention

Keyword: altitude sickness, cardiovascular research, energy expenditure, type 1 diabetes mellitus

Outcome measures

Primary outcome

See above

Secondary outcome

See above

Study description

Background summary

People with diabetes mellitus do need to perform physical exercise in order to keep healthy as long as possible. The Bas van der Goor Foundation seeks to promote sports activities in children and young adults with type 1 diabetes mellitus. This foundation has organized an expedition to the Kilimanjaro, in order to prove that subjects with type 1 diabetes mellitus and in a good condition are able to perform as well as subjects without diabetes mellitus. The medical team has proposed to perform some investigations during this expedition in order to test both the reliability at altitude of the equipment needed for proper treatment of diabetes and the influence of altitude on subjects with type 1 diabetes mellitus.

Study objective

As for the equipment: various investigations will concentrate on the reliability of blood glucose measurement equipment and pumps for CSII at altitude. Furthermore, total insulin requirements, energy expenditure, and glucose curves will be closely assessed during the climb. A Holter registration will be performed throughout the total expedition. Cardiac Echography will be performed at an altitude of 4600 meters

Study design

See also the objective. Pre-expedition tests will be performed at the airforce hypobaric tank installation at Soesterberg. All the other tests are described

in the

Study burden and risks

Very small extra burden, the need to carry approximately 250 grams of extra equipment, some small amount of blood drawing, and a resting cardiac echography at an altitude of 4600 meters.

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

subjects with type 1 diabetes mellitus and a good condition

Exclusion criteria

subjects with insufficient physical condition

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:	Health services research

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	10-10-2008
Enrollment:	16
Type:	Actual

Ethics review

Approved WMO	
Date:	25-08-2008
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

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

NL24307.075.08