The thermophysiological regulation, electrolyte and fluidbalance during a 200-km ice skating race

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON33495

Source
ToetsingOnline

Brief title
Thermoregulation during a 200-km ice skating race

Condition

- Other condition

Synonym
hypothermia

Health condition

sport-gerelateerde gezondheidsproblemen

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: electrolyte and fluidbalance, ice skating, thermoregulation

Outcome measures

Primary outcome

1) Core body temperature (continuous monitoring)

2) Skin temperature (continuous monitoring)

3) Fluid-intake

4) Blood and urine analysis of electrolytes

Secondary outcome

N/A

Study description

Background summary

During outdoor speed skating races, hypothermia is a frequently reported problem. In addition, also the number of subjects with frozen limbs. To date, little is known about the impact of an outdoor ice skating race on thermoregulation. In addition, we also aim at the electrolyte and fluidbalance. A change in fluidbalance will impact upon the core body temperature. Performing the Elfstedentocht (200-km) will have a big impact on the fluid and electrolyte balance, which may cause a decrease of blood flow to the skin and a deterioration of the aerobic performance level. This could influence the risk of hypothermia and freezing of limbs.

Study objective

The overall objective is to determine the thermophysiological strain of a 200-km outdoor ice skating race (elfstedentocht).
The second objective is to examine the relation between

electrolyte-/fluidbalance and the thermoregulation in these conditions.

Study design

Observational study

Study burden and risks

Apart from a questionnaire, heart rate monitor and body weight measurements, all subjects will receive a pill that measures core body temperature. The latter is a safe, valid and user-friendly method to measure core body temperature. The burden for the participants is minimal (time as well as physical), but will lead to important information, necessary for the primary objective of this study. The Department of Physiology has extensive experience in all the afore mentioned measurement techniques. Moreover, all these testing procedures have already been approved in previous studies (CMO-numbers 2007/147, 2007/262 and 2008/227). In addition, before the start en immediately after the finish, blood (10 ml venous) and urine will be analysed to asses the fluid and elektrolyte balance. This is a minimal burden for the participants, while it will lead to important and novel information.

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 year or older
Participant of the Elfstedentocht

Exclusion criteria

All exclusion criteria are related to the use of the temperature pill:
- body weight lower than 36,5 kg
- presence of an obstructive disease of the gastro-intestine. This also includes diverticulosis and inflammatory disease states.
- Operation of the gastro-intestinal tract (excluded; cholecystectomy and appendectomy).
- Magnetic Resonance Imaging (MRI) when the CorTempTM sensor is still in the body.
- pacemaker or any other implanted electronic device

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2010
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	17-03-2009
Application type:	First submission
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	ID
CCMO	NL26685.091.09