Thermophysiological strain and electrolyte and fluid balance in athletes with heat-related problems during the 7-hills run

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

Summary

ID

NL-OMON32869

Source
ToetsingOnline

Brief title
Thermic and electrolyte and fluid balance in heat-related problems

Condition

- Other condition

Synonym
heat-related problems

Health condition

hitte-gerelateerde problemen tijdens fysieke inspanning

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: Core body temperature, Heat-related problems, Running exercise, Sodium levels

Outcome measures

Primary outcome

- core body temperature

- fluid intake and toilet visits

When a core body temperature above 40 degrees is recorded:

- bloed (10 ml venous) and urine assessments of electrolytes (sodium)

Secondary outcome

- Heart rate

- Clothing

Study description

Background summary

Past years, a large number of participants of endurance athletic events (marthons of Rotterdam-London-Boston, dam-tot-dam-loop) ended up in hospital, primarily because of heat-related problems. To the best of our knowledge, only little is known about the impact of endurance events on the thermoregulation. Based on a pilot study, core body temperature during the 7-hills run increases to 39.4 degrees, with some individuals demonstrating an increase above 40 degrees. In general, we aim to gain better insight into the impact of the 7-hills run upon the thermophysiological strain. Specifically, we aim at those subjects that finish the 7-hills run with a core body temperature above 40

degrees. This groups is predisposed to develop (serious) heat-related problems. After identification of these subjects, additional tests will be performed to gain insight into the electrolyte and fluid balance. A fluid disbalance is suggested to be crucial in the development of clincial symptoms and problems when core body temperature rises. This information is essential to prevent and treat heat-related problems during endurance events.

Study objective

The primary goals is to determine the thermophysiological strain during the 7-hills run. Specifically, we are interested in those subjects with a core body temperature above 40 degrees. Based on additional research, we aim to gain better insight into the fluid and electrolyte balance, which may relate to the heat-related problems in these subjects with core body temperatures above 40 degrees.

Study design

Observational study

Study burden and risks

In addition to a questionnaire, heart rate monitor and determination of body weight, subjects receive a sensor pill that record core body temperature. The latter assessment is a safe, valid and 'friendly' method to record core body temperature. The burden of these tests are, physical as well as in time, minimal and privide important information which is necessary for the primary aim of the study.
In the subpopulation of subjects with a core body temperature above 40 degrees, blood and urine will be taken to gain insight into the fluid and electrolytebalance. This is a minimally invasive burden for the subjects, while it provides important 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

- older than 18
- participant of the 7-hills run

Exclusion criteria

obstructive disease of the gastro-intestinal tract, including diverticulitis and inflammatory bowel disease
- previous gastrointestinal surgery, except cholecystectomy and appendectomy
- MRI during the period that the CorTemptm sensor is within the body (e.g. 1 day preceding the 7-hills run, the day of the 7-hills run and 2 days after the 7-hills run)
- subject having a cardiac pacemaker or other implanted electromedical device.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2008
Enrollment:	250
Type:	Anticipated

Ethics review

Approved WMO

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	NL24437.091.08