The physiological strain during a time trial

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Ethical review	Approved WMO
Status	Pending
Health condition type	Body temperature conditions
Study type	Observational invasive

Summary

ID

NL-OMON32382

Source
ToetsingOnline

Brief title
The physiological strain during a time trial

Condition

- Body temperature conditions

Synonym
hyperthermia, overheating

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: hyperthermia, thermoregulation, time trial

Outcome measures

Primary outcome

Coretemperature

Heartrate

Bloodvalues

Uninetest results

Secondary outcome

fluidintake

clothing

Study description

Background summary

Many case reports are written about participants of various sports who collapsed because of a heat stroke. There is a lot of information about the cardiovasculair, metabolic and therminal strain a marathons has on the body. But little is known about the strain a time trial has on the body and the effects of external factors (like clothing and fluidintake) on the thermoregulation. Participation in a marathon differ in many ways with a participation in a time trial. So we can not just use these result on time trial cyclists.

Study objective

The goal of the study is to registrate the cardiovascular, metabolic and thermalstrain during the participation of the WUCC time trial. Besides that we will look at different factors, like the weather, fluidintake and clothing, who possible have an effect on this strain. This information can be used to identify the risks that are connected to participation in a time trial and

where possible reduce these risks.

Study design

observational study

Study burden and risks

The reseach will take place on the day of the time trial and the day before. On both days we take 5 mls of blood through a venipuncture to determine the sodium, potassium, hemglobine and hematocite. This common medical intervention has no risk. The only negative consequence could be an small hematoma. Although, the incidence is low (2 %) and doesn't give any restiction in daily life.

The other measurements (heartrate, bloodpressure, weight, protein/glucose, coretemperature and recording the fluidintake and change of clothing) do not strain, uncomfort or risk for the participant in the research and will only take a small amount of time. The measurements will be taken in a special decorated room at the residence of cyclists and at the start/finish of the time trial. That way the strain on the participants will be reduced to a minimum.

Contacts

Public
Universitair Medisch Centrum Sint Radboud

Geert Grooteplein noord 21
6543 EZ Nijmegen
Nederland
Scientific
Universitair Medisch Centrum Sint Radboud

Geert Grooteplein noord 21
6543 EZ Nijmegen
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

18 years and older
not having an exclusioncriteria

Exclusion criteria

-bodyweight less than 80 pounds
-obstructive disease of the gastro-intestinal tract, including diverticulitis and inflammatory bowel disease
-previeus gastrointestinal surgery, except cholecystectomy and appendectomy
-MRI during the period that the CorTemptm sensor is within the body
-subject having a cardiac pacemaker or other implanted electromedical device

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2008
Enrollment:	40
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	NL22479.091.08