Physiological risks during a marathon; the influence on thermoregulation and fluid balance.

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To monitor the thermoregulatory reponse and the disturbances of the fluid- and electrolyte balance during a marathon. Moreover the incidence of hyperthermia and dehydration is determined, whilst the fluid balance of participants with and without...

Ethical review Approved WMO **Status** Recruiting **Health condition type** Other condition

Study type Observational non invasive

Summary

ID

NL-OMON34335

Source

ToetsingOnline

Brief title

Thermoregulation and fluid balance in marathon runners.

Condition

Other condition

Synonym

heat stroke / dehydration, hyperthermia, hypovolemia

Health condition

hitte en vochtgerelateerde problemen bij 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: Dehydration, Hyperthermia, marathon, sodium balance

Outcome measures

Primary outcome

1 core body temperature changes

2 bodyweight changes

3 fluid intake

4 sodium concentration, plasma volume changes

5 Urine measurements

Secondary outcome

- 1) Heartrate
- 2) Speed
- 3) Ambient conditions (WBGT)

Study description

Background summary

Recent editions of big running-events (dam tot dam run, the marathons in Boston, London and Rotterdam) have suffered of a large quantity of participants that needed hospitalization, mainly because of heat-related problems. Because of that, the physiology department of the Radboud university has done large studies to examine physiological changes during endurance excercise. The most import results were that 25 percent of the participants to the 4-day march in Nijmegen showed a significant change in hydratation state and electrolyte concentrations. In another study we found that 15 percent of the participants of a 15 km run suffered of hyperthermia. The marathon is an event which is an

extreme endurance race on a high intensity. That combination makes it a potential dangerous excercise, because both physiological processes (thermoregulation and water balance) can reach extreme values. Although several studies have been performed in a marathon setting, those have a limited value, because of the small group sizes, homogeneous (well-trained men or women) group-characteristics, its laboratory setting, or temperature measurements using a rectal thermometer. The population of marathon-runners is a heterogeous group of trained, untrainend, healthy people and participants with a history of diseases. Therefore previous results cannot be extrapolated to an event like the marathon.

Study objective

To monitor the thermoregulatory reponse and the disturbances of the fluid- and electrolyte balance during a marathon. Moreover the incidence of hyperthermia and dehydration is determined, whilst the fluid balance of participants with and without hyperthermia will be compared.

Study design

Observational

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. Furthermore blood and urine will be taken to gain insight into the fluid and electrolytebalance and measure the Hematocrit and Hemoglobine concentration. This will be performed by experienced people, which willl minimise the risk of this action. The burden of these tests are, physical as well as in time, minimal and provide important information which is necessary for the primary aim of the study.

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

Participants in the Eindhoven Marathon, older than 18 years of age and not subject to any of the excusion criteria.

Exclusion criteria

- -bodyweight lower than 36,5 kg
- -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 CorTemp sensor is within the body (e.g. 1 day preceding the marathon Eindhoven, during the marathon and 2 days after the marathon)
- 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: Recruiting
Start date (anticipated): 01-10-2010

Enrollment: 100

Type: Actual

Ethics review

Approved WMO

Date: 27-09-2010

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 NL33270.091.10