

Electrolytes and small organic molecules in blood and sweat during an incremental cycling protocol

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON48178

Source

ToetsingOnline

Brief title

Relation between blood and sweat content

Condition

- Other condition

Synonym

Er wordt geen aandoening bestudeerd

Health condition

Geen aandoeningen

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit

Source(s) of monetary or material Support: EU

Intervention

Keyword: Blood, Bodily functions, Composition, Sweat

Outcome measures

Primary outcome

[Na⁺], [K⁺], [Cl⁻], [NH₃⁺], [lactate] in blood and sweat.

Secondary outcome

Level of fitness, age, sex, core temperature, heart rate, skin temperature, subjective measures, whole body sweat rate, urine specific gravity (USG), food intake.

Study description

Background summary

Development of smart wearables has never been as popular as it is nowadays. To reduce the need for invasive and expensive measures of human biomarkers, there is need for continuous and non-invasive measures. Thus far, sweat is the most preferred bodily fluid to use for non-invasive measures, over blood for instance. Sweat originates from the blood plasm. However, the correlation between blood and sweat composition remains relatively unknown. The trajectory from blood plasm to sweat at the skin surface therefore has to be investigated. One can do this by investigating correlation between blood and sweat composition while exercise intensity, for example, differs. Since the relationship between important constituents of blood and phenomena like dehydration is known, the possibly found correlations may link sweat composition to these phenomena.

Study objective

Possible correlations between blood and sweat composition will be investigated. If these correlations exist, sweat composition can be related to phenomena like

dehydration. In this way, invasive measurements may become unnecessary in elite sport and health settings.

Study design

The study consists of 2 measurements at the Vrije Universiteit Amsterdam. During visit 1 participants* maximal oxygen capacity (VO₂ max) will be determined by performing a maximal cycling test in a thermo-neutral condition. The second visit will be an incremental cycling protocol in the climatic chamber, set at 30°C, 30% RH. During this second visit 15 blood and 10 sweat samples will be collected. Physiological parameters body temperature, skin temperature, heart rate and sweat rate will be monitored continuously.

Study burden and risks

It is possible that participants feel warm or uncomfortable during the measurements. To prevent any risk body temperature, heart rate and subjective measures are carefully and continuously monitored. Besides, the experiment will be quit if body temperature exceeds 39.5 °C. The experiment will also be discontinued if the participant feels dizzy or nauseous.

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

- 18-40 years old
- Generally healthy: no cardiac problems (according to NYHA classification), no high blood pressure, no fever or infection, no psychiatric problems, no liver and kidney problems
- Command of the Dutch language
- Fit (actively taking part in sports 3 times a week)
- Body mass index (BMI) 20-25 kg/m²
- Veins suitable for blood sampling at the inspection
- Based on the outcome of the anamnesis form, participants should be rated as low-risk participants

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- Underage
- Older than 40 years
- Smoking
- Use of hard drugs
- Use of specific medicines:
 - * Chronic use of NSAIDs: aspirin, ibuprofen, corticosteroids
 - * Drugs for gastric and intestinal function
 - * Drugs for heart and coronary diseases
- Blood donation six weeks prior to the start of the study
- Pregnancy or breastfeeding
- Sweat pattern condition: hyperhidrosis, hypohidrosis or anhidrosis
- No low-risk classification based on the outcome of the anamnesis form (see appendix xxx)

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 02-10-2019

Enrollment: 12

Type: Actual

Ethics review

Approved WMO

Date: 07-06-2019

Application type: First submission

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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

NL69095.078.19