Exploring the use of an optical sensor for personalized determination of body fluid balance

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Establishment of a quantitative relationship between NIR measurements and body fluid balance in research subjects exposed to accelerated dehydration by cycling exercise on a home trainer. This explorative study will generate detailed information of...

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

Summary

ID

NL-OMON46535

Source
ToetsingOnline

Brief title
Optical sensor for personalized determination of body moisture balance

Condition

- Other condition

Synonym
dehydratation, torrefaction

Health condition

lichaamshydratatie

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: NWO,NovioSmart BV

Intervention

Keyword: Body fluid balance, Optical sensor

Outcome measures

Primary outcome

Establishment of a (quantitative) relationship between diffuse reflectance NIR spectroscopy measurements on the skin (both positively and negatively correlated wavelengths) with the body fluid balance using a limited set of research subjects. Body weight will be used as reference for the body fluid balance. BIA will be used as a second line control. This pilot study will generate detailed information needed to verify the suitability of protocols and methods in order to develop the final protocol for a subsequent main study.

Secondary outcome

Not applicable.

Study description

Background summary

Assessment of the body fluid balance in humans by non-invasive and continuous optical measurements, like near-infrared spectroscopy (NIR) can significantly contribute to the prevention of dehydration in elderly but also in athletes during prolonged endurance exercise. Serious dehydration in elderly may result in cardiac and mental health problems ending up in hospitalization. Personalized early warning of dehydration will contribute to a better life for elderly and a decrease of hospitalization.
For athletes, dehydration of as little as 2% of the body weight can impair aerobic exercise performance. The proper assessment of an athlete*s hydration

status before, during, and after exercise is warranted. Equilibration of water saturation will enhance the sports performance.

Study objective

Establishment of a quantitative relationship between NIR measurements and body fluid balance in research subjects exposed to accelerated dehydration by cycling exercise on a home trainer. This explorative study will generate detailed information of the minimum amount of dehydration which is required to establish a clear difference in NIR signals between the hydrated and the dehydrated state of the athletes.

Study design

Ten research subjects are recruited to participate in this experimental study. Parallel measurements of body weight (hydration status) and NIR of the skin surface are conducted during 90 min. of moderate-intensity cycling exercise and after 60 min of recovery. During the recovery period, research subjects ingest an isotonic sport drink providing 100% of the body weight loss. The relationship between body weight and NIR data will be assessed. As second reference method, bioelectric impedance measurements will be performed at the start, mid-point (90 min.) and end of the study (150 min.) The experimental protocol will be repeated three times.

Intervention

Intervention consists of performing physical exercise.

Study burden and risks

Research subjects will have to cycle 3 times on a cycle ergometer over a period of 6 weeks with a minimum of one week between replicates. There are no additional risks associated with the measurements in this experimental study. The research subjects will have to perform a 90 min bout of cycling exercise at 60-70% of the estimated maximal heart rate (70% HRmax, estimated by equation HRmax = 220 * age). This will results in fatigue, and can give rise to some muscle soreness (in the days) after exercise. However, only physically active and healthy research subjects are selected. Total duration of the experiment will be approximately 3 hours.

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

Healthy and physically active male subjects (self-reported sport participation minimum 2 times per week during the last 6 months), age from 18 to 30 years. Research subjects have to know from their selves that they sweat extensively upon exercise (self-reported by self-estimation). For homogeneity of the study population, only Caucasian males will be included. Moreover differences in skin colours may influence the NIR signal of the skin.

Exclusion criteria

Research subjects who use any medication or (psycho)pharmaceuticals. Research subjects who suffer from chronic or metabolic diseases. Research subject who use pace-makers.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-07-2018
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	SCiO Molecular sensor
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	29-05-2018
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)

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	NL64913.081.18