Variation in measurement results of extracellulair fluid of arms under different measurement conditions using the L-Dex U400

Published: 17-12-2013
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The aim of the study is to determine the variotion in measurments of extracellular fluid of the arm using the L-Dex U400 during different measurement conditions in healthy subjects.

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

Summary

ID

NL-OMON38489

Source
ToetsingOnline

Brief title
Variation in measurement results using the L-Dex U400

Condition

- Other condition

Synonym
Arm volume, Extracellular fluid

Health condition

gezonde proefpersonen

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Bioimpedance Spectroscopy, Extracellualir fluid

Outcome measures

Primary outcome

The primary outcome is variation in measurement results using the L-Dex U400.

Secondary outcome

Not applicable

Study description

Background summary

The L-Dex U400 bio-impedance measuring device which is applied to determin extracellulair fluidr in an extremity. The reliability of the L-Dex U400 under different measurmen conditions, for example different measuring sessions or different observers has not been investigated. Additionally the amount of variation in measurement results due to different conditions has not been determined. Differences in outcomes in patients suffering form early lymph edema (extracellular fluid) cannot be interpreted correctly. Differences could caused by changes in the amount of extracellular fluid, but also by lack of precision in the L-Dex U400. Therefore we want to determine first in healthy subjects what the variation in measurement results obtained with the L-Dex U400 is under different conditions.

Study objective

The aim of the study is to determine the variotion in measurments of extracellular fluid of the arm using the L-Dex U400 during different measurement conditions in healthy subjects.

Study design

The study has a repeated measuremt design.

Measurments (in total 12) wil be performed: a baseline measurement, after a short rest (10 min.), drinking coffee (200ml), change electrodes (another observer) and after moderate exercise (30 minute cycling on a home trainer,50 Watts, 50-60 RPM) and after a final short rest period. In the next measurement session, a week later, the same measurement protocol wil be repeated.

Study burden and risks

The burden to participate is low. The participants have to cycle for 30 minutes 50 Watts, corresponding to cycling to school and/ or work. There are no risks associated with participation.

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 subjects
Age between 18 and 25 years
Par-Questionnaire negative
Informed Consent is signed
Able to attend a measurement session on two days

Exclusion criteria

Not able to attend two measurementsessions
Heart, liver or kidney disorders
Pregnancy

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-03-2014
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	17-12-2013
Application type:	First submission

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

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	NL44871.042.13