Body Composition Validation Study

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PrimaryThis study aims:1) To validate ultrasound (both on the spot & trajectory measurements) against the gold standard 3-compartment model to assess body composition.2) To compare the accuracy of ultrasound to assess body composition with skin…

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

Summary

ID

NL-OMON35857

Source
ToetsingOnline

Brief title
Body Composition Validation Study

Condition

- Other condition

Synonym
Body Composition, the composition of the human body

Health condition

Body Composition

Research involving
Human

Sponsors and support

Primary sponsor: Philips Research
Source(s) of monetary or material Support: Philips Research

Intervention

Keyword: Deuterium Dillution, Ultrasound, Underwater Weighing, Validation

Outcome measures

Primary outcome

The fat percentage a measured by:

- the 3-compartment model (under water weighing and deuterium dilution)

- ultrasound

- skin fold thickness

Secondary outcome

- thoracic impedance as measured by the bio-electrical impedance monitor (BIM)

- body volume a measured by 3D-imaging and under water weighing

Study description

Background summary

Measuring body composition can be done via a wide range of technologies, ranging from highly accurate and expensive to quick and cheaper methods. The current issue is that these technologies are either not accessible for the majority of the people, or provide too low accuracy or demand proper training to be applied correctly.
Ultrasound is a risk free technology, mainly used for medical imaging purposes. This technique is capable of measuring direct thicknesses of tissue layers like subcutaneous adipose tissue and muscle mass. The most commonly used method in literature is similar to the skin fold caliper principle: measuring tissue layer thicknesses on dedicated spots on the human body. Compared to the skin fold caliper method, ultrasound distinguishes between skin and adipose tissue. Additionally, the probe contains pressure sensors to make sure the same pressure is applied constantly. In the future this will help untrained personnel to operate the device, and even make sure the probe is kept perpendicular to the skin.
A second, novel method is tested in this trial. Instead of on the spot measurements, trajectories will be scanned to gain considerably more tissue layer information compared to just spot measurements which we expect to results

in a significant gain in accuracy. These trajectories include the most commonly used spots as well. To control for scanning speed, a laser-based speed sensor is added to the experimental set up.
The secondary objective of this trial is to test a thoracic impedance measurement vest, designed to be used in the home environment (i.e. without supervision or prior expertise). Measurements of thoracic impedance can be used to evaluate fluid retention in the lung in patients with congestive heart failure. However, impedance measurements can be affected by a number of factors (electrode-skin contact, body composition, etc.). In order to obtain meaningful and comparable thoracic impedance measurements between subjects, it would be desirable to remove uncertainty due to measurable physiological factors. By investigating the relationship between body composition and thoracic impedance in healthy subjects with a range of BMI, we aim to model the effect of body composition and eventually remove this effect from the impedance measurements. This will allow thoracic bio-impedance measurements to be normalised and therefore comparable between subjects.

Study objective

Primary
This study aims:
1) To validate ultrasound (both on the spot & trajectory measurements) against the gold standard 3-compartment model to assess body composition.
2) To compare the accuracy of ultrasound to assess body composition with skin fold measurements.
3) To develop new models for assessing body composition by ultrasound technology (both on the spot & trajectory measurements), by using the 3-compartment model as the reference technique.

Secondary
In addition to the main aims of the study, a parallel and independent objective will be:
4) To evaluate the effect of body composition (i.e. total body fat-free mass and fat mass) on inter-individual variability in thoracic bio-impedance.
5) To investigate the accuracy of total body volume measurements using 3D imaging in comparison to underwater weighing.

Study design

The study will be a cross-sectional observational study.

Study burden and risks

All techniques used specifically for this study are non-invasive. All other techniques are of a very low risk and place little burden on the subject. Subjects will be informed about the results of the study and will receive their

personal data.

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, between the age of 18 and 70, BMI range between 18.5 and 40 kg/m2. Ethnicity: Caucasian

Exclusion criteria

• Participants that have any form of abnormality in body composition, such as amputation, or abnormal hydration status.

• Pregnant women.
• Participants that have known nickel allergies.
• Non-intact skin (e.g. eczema), neurodermatitis or sensitive skin
• Participants with active medical implants (e.g. pacemakers, implanted cardioverter defibrillators or implanted devices measuring intrathoriacic bio-impedance).

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-08-2011
Enrollment:	60
Type:	Anticipated

Ethics review

Approved WMO

Date:	16-09-2011
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL35639.068.11