# A new approach to calculate energy expenditure as assessed with doubly labelled water during high energy turnover: a proof of concept study.

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

### Summary

### ID

NL-OMON48427

**Source** ToetsingOnline

Brief title doubly labelled water during high energy turnover

### Condition

• Other condition

**Synonym** this is not disease related research

#### **Health condition**

geen aandoeningen

#### **Research involving**

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Human

### **Sponsors and support**

Primary sponsor: Universiteit Maastricht Source(s) of monetary or material Support: Ministerie van OC&W

### Intervention

Keyword: doubly labelled water, energy expenditure, room calorimeter

### **Outcome measures**

#### **Primary outcome**

The primary outcome parameters are CO2-production as assessed with doubly

labelled water and with the respiration chambers.

#### Secondary outcome

The secondary outcome spontaneous physical activity (or body movement) as

assessed with accelerometry.

## **Study description**

#### **Background summary**

Doubly labelled water is considered the gold standard technique to assess daily life energy expenditure over a period of several days up to 3 weeks. The technique is based on the principle that when a dose of water containing two stable isotopes (2H and 18O) is given to a subject, the 2H isotope will be eliminated from the body as water (H2O) and the 18O isotope will be eliminated as both water and carbon dioxide (CO2). The difference in disappearance rates of both isotopes is hence a measure of CO2-production, from which energy expenditure can be calculated. In principle, there are two different calculation techniques used to determine the dilution space (distribution volume) of these isotopes in the body. The way the dilution space is calculated also affects the calculated CO2-production. These two techniques are generally referred to as the \*plateau\* technique and the \*slope-intercept\* technique. In the current study, we investigate the possibility to calculate CO2-production more accurately with a newly developed approach which will be referred to as \*overnight slope\* technique. This technique will also allow to calculate day-to-day variability in energy expenditure, rather then just energy expenditure over the entire observation period (i.e. usually 2 weeks).

#### Study objective

The aim of this study is to test whether our new \*overnight slope\* technique to calculate the isotope dilution space results in a more accurate measurement of doubly labelled water assessed CO2-production, which will be compared to indirect calorimetry (respiration chambers) as the gold standard.

### Study design

Methodological proof of concept study

### Study burden and risks

The study poses a very low risk but a high burden for the subjects. As doubly labelled water assesses CO2-production over several days (at least 5) and the respiration chambers are being used as the reference technique, subjects will have to reside inside the respiration chambers for 5 consecutive days. This does not pose any risks but is a considerable burden for the subject. Also, subjects will be cycling for several hours per day inside the chamber in order to obtain a high physical activity level (PAL = 2.5 - 3.0). Because of this burden, subjects will be allowed to exit the chamber every evening for approximately 30 min in order to take a shower. CO2-production from this 30 min outside the chamber will be estimated based on measured CO2-production over 30 min during the day when not exercising.

Doubly labelled water is safe for use in humans and the required dose for energy expenditure assessment does not pose any risks to the subjects. Only urine and saliva samples will be taken.

To monitor all movement inside the chamber, wearable sensors (accelerometers) will be used. Physical activity as assessed with these accelerometers will be used to assess biological variation in spontaneous physical activity over the different days. Accelerometers pose a minimal burden to the subject

# 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 male or female
- Age 18-45 years
- Have a high physical activity level (participate in endurance exercise at least 3/week)

### **Exclusion criteria**

- Subjects suffering from claustrophobia

- Subjects with any known medical condition affecting their capacity to perform long term endurance exercise (e.g. cardiovascular disease), as determined by a medical questionnaire - Smoking

#### - Smoking

### Study design

### Design

Study type:Observational non invasiveMasking:Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Other

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	05-04-2019
Enrollment:	10
Туре:	Actual

### **Ethics review**

Approved WMO	
Date:	01-04-2019
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 CCMO

**ID** NL68773.068.19