

Measurement of changes in ventilation at various levels of inspired carbon dioxide with two methodes.

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Ethische beoordeling	Niet van toepassing
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28684

Bron

Nationaal Trial Register

Verkorte titel

HCVR study

Aandoening

healthy subjects

Ondersteuning

Primaire sponsor: Eijsvogel, M.M.M.; Enschede; The Netherlands

Overige ondersteuning: fund = initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main study endpoint is the reproducibility of the measurements. Sensitivity slope (L/min per kPa) of the curve is calculated by means of linear regression. To assess the repeatability of both methods, the ICC is calculated between the paired CO₂ sensitivity slopes of the first and second rebreathing measurement and between the first and second steady-state measurement

Toelichting onderzoek

Achtergrond van het onderzoek

Effects of increasing/decreasing levels of CO₂ on ventilation can be studied using the hypercapnic ventilatory response (HCVR). In various patient groups the HCVR is disturbed. Two methods are known to measure the HCVR, the rebreathing and steady-state method. Both methods can measure the ventilation response to CO₂, therefore in this study the two methods will be compared. Computer controlled systems are not available for use, due to high costs to persuade or built them. In this study two self-made apparatuses are built, based on literature. The aim of the study is to find out which method is to be implemented in the clinic, as a diagnostic tool, on basis of the repeatability of both tests.

Doel van het onderzoek

The primary objective is to investigate whether the rebreathing apparatus or the steady-state apparatus should be used as a diagnostic tool in the MST. The primary objective is answer by means of sub questions, which involve; the repeatability of both methods, experiences of the subjects, costs and time duration of both methods.

Onderzoeksopzet

Measurements are performed with 20 subjects. Two appointments per subject are made, the second measurement is within 5-9 days after the first. At both appointments HCVR is measured with both methods. At the first appointment the order is determined with a randomisation list (rebreathing steady-state or steady-state rebreathing).

Onderzoeksproduct en/of interventie

not applicable

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

healthy, adult aged between 18 and 65

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

history of cardio-pulmonary disease, neuro(muscular) disease, and/or kyphoscoliosis; unable to understand and read the English or Dutch language; drug abuse; use of respiratory stimulants or depressant; and pregnant women

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Enkelblind

Controle: N.v.t. / onbekend

Deelname

Nederland
Status: Werving gestopt
(Verwachte) startdatum: 22-03-2017
Aantal proefpersonen: 20
Type: Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing
Soort: Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 45318
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6115
NTR-old	NTR6254
CCMO	NL60541.044.17
OMON	NL-OMON45318

Resultaten