Correlation and level of agreement between echocardiography and a new inert gas rebreathing technique in estimating cardiac output

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We would like to perform a study in which first the level of agreement and the correlation between echocardiography and the new rebreathing technique in estimating cardiac output will be determined.

Ethical review	Approved WMO
Status	Pending
Health condition type	Pregnancy, labour, delivery and postpartum conditions
Study type	Observational non invasive

Summary

ID

NL-OMON30267

Source
ToetsingOnline

Brief title
validationstudy inert gas rebreathing technique

Condition

- Pregnancy, labour, delivery and postpartum conditions

Synonym
history of preeclampsia

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cardiac output, echocardiography, inert gas rebreathing technique, validation study

Outcome measures

Primary outcome

Correlation and level of agreement between echocardiography and the rebreathing

technique.

Secondary outcome

geen

Study description

Background summary

Pregnancy induces major maternal cardiovascular changes, which are necessary for the normal course of pregnancy. The hyperdynamic circulation of pregnancy develops in early gestation, but the increase in cardiac output continues up to the end of pregnancy.
However, most of these studies are performed with echocardiography, but although Doppler ultrasound is a non-invasive and safe method to measure cardiac output, there are some theoretical and practical constraints to Doppler cardiac output estimations. Recently, a new foreign gas rebreathing technique is developed, which seems to be a fast and easy way of measuring cardiac output. Due to the use of minor concentrations of N2O and SF6, this method can safely be used.
Yet, a comparison between echocardiography and the rebreathing technique seems te be a logical next step.

Study objective

We would like to perform a study in which first the level of agreement and the correlation between echocardiography and the new rebreathing technique in estimating cardiac output will be determined.

Study design

To determine the correlation and level of agreement between cardiac output measured by the rebreathing technique and by echocardiography, 20 female non-pregnant patients will be subjected to both techniques. All women will be recruited from the postpartum follow-up, who will normally receive echocardiography as part of the postpartum evaluation after a vascular complicated pregnancy.

Study burden and risks

The concentrations of the gases inspired during the Innocor measurements are completely safe in a non-pregnant situation.However, it should be emphasized that there is an interval of 5 minutes between the measurements, to prevent an accumulation of gases in the pulmonary blood stream. Additionally, we try to create a quiet and comfortable environment during the measurements.

Contacts

Public
Universitair Medisch Centrum Sint Radboud

Postbus 9101
6500 HB Nijmegen
Nederland
Scientific
Universitair Medisch Centrum Sint Radboud

Postbus 9101
6500 HB Nijmegen
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

history of vascular complicated pregnancy, 18-35 yr, >6 months postpartum

Exclusion criteria

pulmonary abnormalities

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):	01-12-2006
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL15166.091.06