Validation of maternal cardiac output trending with impedance cardiography against transthoracic Doppler echocardiography in healthy pregnant women.

Published: 25-07-2017
Last updated: 15-04-2024

ICG allows continuous, non-invasive monitoring of the CO. ICG is a method that detects changes in thoracic electrical bioimpedance between simple skin electrodes, together with a conventional ECG. To estimate CO, it uses complex algorithms based on…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Maternal complications of pregnancy
Study type	Observational non invasive

Summary

ID

NL-OMON45637

Source
ToetsingOnline

Brief title
ICG-trending

Condition

- Maternal complications of pregnancy

Synonym
healthy pregnancy

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Impedance cardiography, Pregnancy, Transthoracic echocardiography, Validation

Outcome measures

Primary outcome

Validation of ICG for the assessment of CO in trending ability (relative *CO)

during pregnancy using TTE, using the 4-quadrant plot, and calculating the

concordance rate, angular bias and radial limits of agreement

- Hypothesis: ICG accurately allows CO trending during pregnancy as compared

to TTE.

Secondary outcome

Assessing agreement between ICG and TTE for individual CO measurements in

pregnant women.

Study description

Background summary

During healthy pregnancy, the maternal cardiovascular system changes to contribute to optimal growth and development of the foetus and help to protect the mother from risks. Major hemodynamic changes induced by pregnancy include increase of the maternal cardiac output (CO) above non-pregnant levels. CO is a functional parameter, reflecting the total demand placed on the cardiovascular system. CO is defined as the volume of blood pumped into the aorta per unit time and is calculated as the product of stroke volume (SV) and heart rate (HR). Direct and indirect causes of maternal mortality and morbidity like preeclampsia and haemorrhage and cardiac diseases, have been associated with substantial changes in CO. Nowadays, monitoring maternal cardiovascular function is limited to indirect parameters of maternal cardiovascular function

including heart rate and blood pressure. Measuring the CO could be a major help in directing management and treatment in pregnant woman with cardiac pathology and in pregnancy complications.

Invasive techniques such as Intermittent Bolus Pulmonary Artery Thermodilution, continue to be the gold standard to measure CO. Since this method requires right heart catheterization with a pulmonary artery catheter, it is associated with a variety of complications to the participant. This method is controversial on account of its invasiveness and with inherent risks. A non-invasive continuous measurement could be of major value.

Transthoracic echocardiography (TTE) is a clinically established non-invasive diagnostic method that provides assessment of cardiac structure and function. CO can be calculated with two-dimensional pulsed wave Doppler as the product of the cross-sectional area and and left ventricular outflow tract velocity time integral (LVOT VTI). This method has been validated to measure CO against invasive techniques in and outside pregnancy. However, this technique has its limitations. TTE is dependent on the operator*s skill in acquiring images taking correct measurements and continuous assessment is time consuming.

Study objective

ICG allows continuous, non-invasive monitoring of the CO. ICG is a method that detects changes in thoracic electrical bioimpedance between simple skin electrodes, together with a conventional ECG. To estimate CO, it uses complex algorithms based on assumptions regarding the thoracic dimensions and shape to convert changes in thoracic impedance into volume changes. In theory, the specific pattern of major physiological adaptations of the pregnant body could influence these assumptions. Physioflow, the device we will use for ICG, was designed to monitor performing athletes, and is thereby equipped with a high signal stability. On that account it can be of value in woman during both pregnancy and labour, which puts an enormous strain on the maternal cardiovascular function. Although there have been numerous validation studies of methods of continuous CO measurement, the majority evaluated the measurement of the actual value of CO. Less than one-fifth of the studies addressed CO trending. Although the accuracy of ICG for absolute CO values appears moderately convincing, it is generally agreed to be capable of trend analysis. However, this technique has not been validated in pregnancy.

As a result, further validation of ICG trending ability during pregnancy is required. We aim to examine the agreement in CO trending between ICG and the clinically established method of TTE in a cohort of healthy pregnant woman. To induce changes in the CO during our measurements, we will submit pregnant women to a limited exercise.

Study design

A prospective comparative study with non-invasive techniques will be performed in order to compare CO trending by ICG with TTE. This trial will be conducted at a tertiary care center, Erasmus University Medical Center Rotterdam. We propose a maximum duration of the study of six months.

Study burden and risks

Burden associated with participation exists of one investigation for an estimated time of 30 minutes. The patients will be examined with ICG and TTE in the left lateral decubitus position in all measurements. After the baseline measurement, participants will exercise on a home trainer until their heart rate rises up to 70% of their maximum heart rate. When this limit is reached, participants will exercise at this heart rate for 1 minute. Subsequently the second measurement takes place. When the heart rate decreases to <20% of the maximum heart rate, the last measurement will be performed. Moreover, maternal data will be collected during participation, including the blood pressure and measured height and weight to determine current BMI. Self-reported age, weight prior to conception, gravidity and parity will be obtained. There is no risk associated with participation for mother and foetus. There is no individual benefit for participants.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Wytemaweg 80
Rotterdam 3015CN
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Wytemaweg 80
Rotterdam 3015CN
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Women without history or symptoms of cardiovascular diseases with a normal, uncomplicated singleton pregnancy, aged *18 years with informed consent.

Exclusion criteria

- Any known pre-existing cardiac, hypertensive or renal disease
- Any contraindication for exercise
- Multiple pregnancy
- Labouring pregnant women
- Not regularly attending scheduled obstetric appointments

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-07-2017
Enrollment:	43
Type:	Actual

Medical products/devices used

Generic name:	impedance cardiography; Physioflow
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	25-07-2017
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL58545.078.16