Differences in response of hemodynamic parameters between pregnant and non-pregnant women during a cardiopulmonary exercise test.

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We aim to examine the differences in response of hemodynamic and ventilatory parameters between women in their first trimester of pregnancy and non-pregnant women during a CPET.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Maternal complications of pregnancy
Study type	Observational invasive

Summary

ID

NL-OMON46409

Source
ToetsingOnline

Brief title
Hemodynamic response in pregnancy.

Condition

- Maternal complications of pregnancy

Synonym
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: Exercise, Hemodynamics, Impedance cardiography, Pregnancy

Outcome measures

Primary outcome

Differences in response of cardiac output (*CO) during a CPET, measured with ICG (by Physioflow), between pregnant and non-pregnant women.

Secondary outcome

Differences in (response of) hemodynamic parameters, ventilation parameters and aerobic capacity during and after a CPET (measured with ICG, breath-by-breath analysis, a finger prick blood sampling and a pulse oximeter) between pregnant women and non-pregnant women. The parameters that will be measured or calculated are:

- Heart rate
- Blood pressure
- Stroke volume
- Left cardiac function
- Systemic vascular resistance
- Velocity index
- Sensitivity index submaximal (VO2 / stroke volume index)
- Oxygen saturation
- Gas exchange (VO2 and VCO2)
- PetCO2 (End Tidal CO2)
- EqCO2 (Equivalent CO2)

- Anaerobic treshold

- Lactate level in capillary blood

Study description

Background summary

Normal pregnancy is characterized by a rise in cardiac output (CO) and a drop in heart rate (HR) and systemic vascular resistance (SVR) already in the first trimester of pregnancy, in order to cope with the increased demands of oxygen and nutrient to allow appropriate growth of a fetus. This cardiac adaptation to pregnancy can be compared to a nine month lasting moderate exercise. It is thought that in women who develop placenta-related pregnancy complications (PPC) an increased risk for cardiovascular disease is unmasked by the stressed state of pregnancy. To study differences in the cardiovascular adaptation to pregnancy between women who will or will not develop PPC it is necessary to gather insight in normal values of hemodynamic parameters in pregnant and non-pregnant women. A cardiopulmonary exercise test (CPET) is a reliable test to study the responses of the cardiovascular and respiratory system during physical stress. Impedance cardiography (ICG) allows continuous, non-invasive monitoring of several hemodynamic parameters, including cardiac output, stroke volume and SVR. Physioflow is a device that can be used for ICG and is equipped with high signal stability. It is therefore very suitable to be used during a CPET. However the differences in patterns of hemodynamic parameters measured with ICG during CPET between pregnant women and non-pregnant women have not yet been investigated.

Study objective

We aim to examine the differences in response of hemodynamic and ventilatory parameters between women in their first trimester of pregnancy and non-pregnant women during a CPET.

Study design

A prospective comparative study, conducted at Erasmus University Medical Centre Rotterdam. There will be no randomisation or blinding.

Study burden and risks

Burden associated with participation exists of one investigation for an estimated time of 30 minutes. Participants will exercise on a cycle ergometer, according to a Rapid AccuMulation protocol (RAMP), until their heart rate rises

up to 70% of their maximum heart rate. During the CPET measurements take place, using ICG, pulse oximeter, blood pressure meter and a breath-by-breath mask. Before and after the CPET a blood lactate will be assessed, using a single finger prick. The exercise test will not take place when the participant has high blood pressure (>140mmHg systolic and/or >90mmHg diastolic) or low oxygen saturation (<94%) during baseline measurements. The tests and measurements are validated and are considered safe for pregnant women, their fetus and non-pregnant women. There is no individual benefit for participants. In case of any adverse finding women will be referred to specialized care (i.e. cardiologist, gynaecologist).

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

- 20 pregnant women, <13 weeks pregnant
- 20 non-pregnant women
- Age 18-40 years

Exclusion criteria

- Any known pre-existing cardiovascular, respiratory, hypertensive or systemic disorder
- Orthopaedic impairment that compromises exercise performance
- History of placenta-related pregnancy complications (PPC)
- Multiple pregnancy
- Smoking or quit smoking <3 months

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-05-2018
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	16-05-2018
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	NL65204.078.18