Functional cardiac adaptation during and after pregnancy

Published: 14-01-2022
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The aim of this study is to determine functional parameters of the maternal heart during the lactation period by echocardiography and to correlate these functional parameters with circulating hormones.

Ethical review	Not approved
Status	Will not start
Health condition type	Pregnancy, labour, delivery and postpartum conditions
Study type	Observational invasive

Summary

ID

NL-OMON50433

Source
ToetsingOnline

Brief title
Pregnancy-Induced Cardiac adaptatiON (preg-ICON).

Condition

- Pregnancy, labour, delivery and postpartum conditions

Synonym
Functional cardiac adaptation

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Nederlandse Hartstichting

Intervention

Keyword: Cardiac function, Pregnancy

Outcome measures

Primary outcome

To determine Echocardiography parameters to be obtained will include LVEF, left ventricular dimensions, left ventricular mass index, septal wall thickness, posterior wall thickness, systolic function), LV mass, left atrial (LA) volume and e*. If available, other echocardiographic parameters, including right atrial dimensions, parameters of diastolic dysfunction (i.e., E, A, E/A ratio, deceleration time, e* and E/e* ratio) and valve (dys)function will also be evaluated.

- to obtain a descriptive biomarker profile of women during and after pregnancy, but especially to differentiate lactating women from non-lactating women.

- Proteomics will be used to determine unbiased profiles pertaining to circulating factors in the collected blood samples

Secondary outcome

-The serum collected will be added to culturing conditions of in vitro models that are used as surrogates for the human heart. These models are based on cultured cardiomyocytes that have been generated from pluripotent stem cells. In these in vitro studies, gene expression, protein expression, cell size, and metabolic function will be determined as functional parameters. These cells

have been obtained as part of a previous study for which ethical approval was

given (METc2014/104).

Study description

Background summary

Pregnancy poses a stress test for the maternal heart and is associated with various physiological changes over the course of pregnancy and during lactation. For example, blood volume increases significantly which leads to volume overload for the heart and subsequent cardiac hypertrophy and angiogenesis. Hormones drive metabolic switches in almost all organs. It is unknown how these challenges affect the maternal heart and how quickly these effects dissipate after delivery.

Study objective

The aim of this study is to determine functional parameters of the maternal heart during the lactation period by echocardiography and to correlate these functional parameters with circulating hormones.

Study design

This observational study pertains to healthy women during pregnancy and after delivery.
Group 1: Breastfeeding participants after delivery
Group 2: Participants who are not breastfeeding after delivery.

Study burden and risks

Participants will be invited to visit the UMCG at four to five different times for echocardiography and collection of blood.

These visits will be scheduled for the nursing group at gestational week 20 and, week 36-38, 10 weeks postpartum and when breastfeeding is stopped postpartum, and 10 weeks after cessation of lactation.

The control group will be invited for visits at gestational week 20 and week 36-38, 10 weeks postpartum, and 6 months postpartum.

There are no risks associated with echocardiography and venipuncture may cause minor discomfort at the time of blood collection and may result in minor

hematoma formation, this is seen as negligible risk.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Inclusion criteria

- Ages between 18 * 40 years.
- Healthy pregnant women.
- Parity under or equal to 2 (no more than 2 previous advanced pregnancies)

Exclusion criteria

- Complications during current pregnancy or during a previous pregnancy that may affect the current pregnancy including HELLP syndrome and pre-eclampsiaia.
- Twin pregnancy.
- Use of prescribed medication.
- Unable to understand study procedures.

- Unable or unwilling to provide informed consent.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	100
Type:	Anticipated

Ethics review

Not approved

Date:	14-01-2022
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL79238.042.21