Cardiovascular and metabolic health after the challenge of pregnancy: development and evaluation of a strategy of individual health risk appraisal and tailored intervention

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1. To develop a postpartum strategy of appraisel of cardiovascular and metabolic health after pregnancies, complicated by PE, IUGR or GD.2. To develop and evaluate the feasibility of a lifestyle intervention strategy.3. To design a study proposal...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Lifestyle issues
Study type	Interventional

Summary

ID

NL-OMON30027

Source
ToetsingOnline

Brief title
PRO-ACTIVE

Condition

- Lifestyle issues
- Vascular disorders NEC

Synonym
cardiovasculair diseases, lifestyle

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: ZonMw,DSM Food Specialties

Intervention

Keyword: cardiovasculair disease, gestational diabetes, lifestyle intervention, preeclampsia

Outcome measures

Primary outcome

Development and feasibility of a lifestyle intervention strategy to prevent

type 2 diabetes mellitus and cardiovascular disease.

Secondary outcome

Adherence to the lifestyle intervention strategy and reason of lack of

adherence.

Weightloss.

Study description

Background summary

Secondary and primary prevention of cardiovascular disease (CVD) and type 2 diabetes mellitus (DM2) are difficult to achieve, mainly because of the lack of an effective strategy to identify high-risk individuals at a young age. This study uses the theory of pregnancy being a cardiovascular and metabolic stress-test. Complications of pregnancy, such as preeclampsia (PE), intrauterine growth restriction (IUGR) and gestational diabetes (GD), are symptoms of increased cardiovascular or metabolic risk at later life. Lifestyle interventions, and if necessary pharmakotherapeutic treatment, are possibly the best way to reduce this risk. The complicated pregnancy creates a window of opportunity for lifestyle interventions.

Study objective

1. To develop a postpartum strategy of appraisel of cardiovascular and metabolic health after pregnancies, complicated by PE, IUGR or GD.

2. To develop and evaluate the feasibility of a lifestyle intervention strategy.

3. To design a study proposal for an effect evaluation of the developed lifestyle intervention strategy.

Study design

During the first part of the study the lifestyle intervention strategy will be developed for women with a complicated pregnancy (PE, IUGR, GD). New techniques like 'computer based tailored intervention' will be used.
Information will be gathered by performing a search of the literature and by focusgroup interviews.

Intervention

All participants will be offered the developed lifestyle intervention strategy. In case of a medical condition, like hypertension or diabetes, pharmacotherapeutic treatment will be applied by protocol.

Study burden and risks

Participants visit the outpatient clinic 7 times during 14 months. 6 visits will consist of venapuncture, weighting and measurement of the participant. 1 visit will consist of feedback. During 3 visits a questionnaire concerning lifestyle will be filled in by the participant.
The lifestyle intervention strategy must yet be developed. It might consist of some extra visits to the outpatient clinic.

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

Recently given birth
*=< 6 weeks postpartum
The recent pregnancy was complicated by at least one of the following aspects:
*Preeclampsia
**bloodpressure >= 140/90 mmHg and
**proteinuria >= 0,3 gr/24 hours and
**gestational age at time of diagnosis >= 20 weeks
*intrauterine growth restriction due to placental insufficiency
**abdominal circumference <5th percentile and
**pathological doppler velocity pattern in umbilical artery
***pulsatility index > 95th percentile or
***absent or reversed enddiastolic flow
*gestational diabetes
**2 hours post-load (75 gr) glucose > 7,8 mmol/l
age at delivery >= 18 years
be master of dutch spoken and written language

Exclusion criteria

preexisting pathology, before indexpregnancy
*kidneydisease
*type 1 and 2 diabetes mellitus
*diagnosed with ischemic cardiovascular disease
*diagnosed with congenital heartdefect without hemodynamic consequences
intrauterine growth restriction, not due to placental insufficiency
*intrauterine infection

*congential malformations

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2006
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO

Date:	22-08-2006
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	NL11603.078.06