IMproved Pregnancy Outcomes by Early Detection; personalised medicine for pregnant women: novel metabolomic and proteomic biomarkers to detect pre-eclampsia and improve outcome.

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

Summary

ID

NL-OMON40138

Source
ToetsingOnline

Brief title
IMPROvED

Condition

- Maternal complications of pregnancy
- Vascular hypertensive disorders

Synonym
hypertension in pregnancy, toxemia

Research involving
Human

Sponsors and support

Primary sponsor: University College Cork, Ireland
Source(s) of monetary or material Support: EU□s Seventh Framework Programme for Research (FP7)

Intervention

Keyword: metabolomics, prediction, pre-eclampsia, proteomics

Outcome measures

Primary outcome

Pre-eclampsia

Spontaneous pre-term birth

Small for gestational age babies

Secondary outcome

Early onset pre-eclampsia

Multisystem complications of pre-eclampsia

Pre-eclampsia with severe fetal or neonatal complications

Major neonatal morbidity in preterm infants

Major neonatal morbidity in term infants

Pre-eclampsia with severe maternal complications

Pre-eclampsia with either severe maternal copmlication or severe fetal or

neonatal complications

Early onset SGA (small for gestational age)

SGA (small for gestational age) with severe fetal or neonatal complications

Early onset spontaneous preterm birth

Spontaneous preterm birth with severe fetal or neonatal complications

Spontaneous preterm birth with PPROM

Spontaneous preterm birth without PPROM

Study description

Background summary

1 in 20 first time pregnancies are complicated by pre-eclampsia, the leading cause of maternal death in Europe. No clinically useful screening test exists; consequently clinicans are unable to offer targeted suveillance or known/emerging preventative strategies.

IMPROvED Consortium members have pioneered a personalised medicine approach to identifying blood-borne biomarkers through recent technological advancements, especially in the field of mass spectrometry and the comprehensive mapping of the blood metabolome and proteome.

The application of new technologies to identify 'at risk' patients in early pregnancy will allow stratified care with personalised fetal and maternal surveillance, early diagnosis and timely intervention. This will lead to significant health economic saving and moreover an accurate predictive test would be a crucial step in reducing the life-threatening complications of the disease.

Study objective

The prime objective of the IMPROvED project is to develop a clinically robust predictive blood test for pre-eclampsia, using innovative technologies and utilising novel metabolite and protein biomarkers.

This blood test is targeted to all first time mothers during early pregnancy to determine their risk for this major pregnancy complication.

The IMPROvED study will:
1. Determine whether prototype predictive assays and algorithms translate to the clinical environment
2. Establish a residual biobank that can be accessed by the European scientific communtiy for high quality research into the cause and prevention of adverse

pregnancy outcomes

Study design

5000 first time mothers will be recruited over the course of 2 years to academic medical centres across Europe (Ireland, UK, the Netherlands, Sweden, and Germany), in a phase IIa prognostic multicentre hospital-based clinical study.

Six recruitment sites (all with high patient-throughput) have been selected on the basis of investigator expertise and background in pre-eclampsia research.

Pertinent and detailed clinical data will be collected, and blood samples taken in the first trimester, at 15, 20 and 34 weeks* gestation. Women will then be followed throughout their pregnancies and pertinent outcomes will be recorded.

Study burden and risks

Four times venipuncture during pregnancy. This will be combined with the blood sample in the context of the clinical care if possible. This procedure has a minimal risk to the participant.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

nulliparous women
16 year or older
singleton pregnancy
between 9+0 and 16+6 weeks gestation

Exclusion criteria

unsure term of pregnancy, 3 or more miscarriages or terminations, known or suspected fetal anomaly, essential hypertension or hypertension at booking, diabetes, renal disease, Systemic Lupus Erythematosus, Anti-phospholipid Syndrome, Sickle Cell Disease, HIV positive, Hepatitis B or C positive, major uterine anomaly, cervical suture in situ, knife cone biopsy, long term steroids, treatment low-dow aspirin/LMVW heparin

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-03-2014
Enrollment:	1000

Type:	Actual

Ethics review

Approved WMO Date:	26-07-2013
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	01-11-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	03-03-2014
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	29-07-2014
Application type:	Amendment
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
ClinicalTrials.gov	NCT01891240
CCMO	NL44426.078.13