Analysis of gene-environmental factors before and early in pregnancy for predicting pregnancy complications

Published: 18-12-2013
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This research aims to determine factors involved in subfertility and serious pregnancy complications that arise early in pregnancy. Due to increased insight into the pathogenesis of these conditions, primary prevention should ultimately be possible.

Ethical review	Positive opinion
Status	Other
Health condition type	Foetal complications
Study type	Observational invasive

Summary

ID

NL-OMON25560

Source
Nationaal Trial Register

Brief title
PREDICT

Condition

- Foetal complications

Synonym
Pregnancy, puerperium and perinatal conditions

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC
Source(s) of monetary or material Support: SSWO

Intervention

- Other intervention

Explanation

Outcome measures

Primary outcome

Fertility parameters, embryonic, fetal and placental growth parameters

Secondary outcome

Maternal and paternal health and diseases, epigenetic profiles in parents and child

Study description

Background summary

This study will lead to a better understanding of the pathogenesis of these diseases, an improved (already preconception) risk selection and possibly ultimately result in primary and secondary preventive strategies with regard to subfertility, pregnancy complications, and cardiovascular diseases later in life.

Study objective

This research aims to determine factors involved in subfertility and serious pregnancy complications that arise early in pregnancy. Due to increased insight into the pathogenesis of these conditions, primary prevention should ultimately be possible.

Study design

It is an observational cohort study that uses the data collected in the context of regular care as much as possible. Women can be included before pregnancy (preconception) and until 10 weeks of pregnancy.

Intervention

Not applicable

Study burden and risks

Venipuncture are part of the study and have minimal risks. There are ultrasound examinations and questionnaires which take time.

Contacts

Public
Erasmus MC, Erasmus University Medical Center Rotterdam
R.P.M. Steegers-Theunissen

The Netherlands
Scientific
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The Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Adults (18-64 years)

Inclusion criteria

- You have a child wish
- You are less than 10 weeks pregnant
- You are 18 years or older
- You are pregnant with a singleton
- You are being monitored by the Department of Obstetrics & Gynecology of Erasmus MC or you
  have been monitored by the Department Reproductive Medicine of Erasmus MC

Exclusion criteria

- Oocyte donation
- You are not the biological father of the (unborn) child

Study design

Design

Study phase:	N/A
Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	14-01-2009
Enrollment:	0
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Approved WMO

Date:	12-10-2009
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
NTR-new	NL4115
NTR-old	NTR4356
Other	METC-nummer: 2004-227 : TRC-nummer: R32

Study results

Summary results

• Steegers-Theunissen RP, Verheijden-Paulissen JJ, van Uitert EM. et al. Cohort Profile: The Rotterdam Periconceptional Cohort (Predict Study). Int J. Epidemiol. 2016; 45;374-81
• Melek Rousian, Sam Schoenmakers, Alex J Eggink, Dionne V Gootjes, Anton HJ Koning, Maria PH Koster, Annemarie GMGJ Mulders, Esther B Baart, Irwin KM Reiss, Joop SE Laven, Eric AP Steegers, and Régine PM Steegers-Theunissen Cohort Profile Update: the Rotterdam Periconceptional Cohort and embryonic and fetal measurements using 3 D ultrasound and virtual reality techniques. Int J. Epidemiol. 2021 Oct; 50(5): 1426-1427l.