Advanced prenatal screening in the first trimester of pregnancy: ADAM12 and PP13 as new screening markers for aneuploidy and adverse pregnancy outcome.

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The RIVM, UMCU and VUmc collectively will perform a prospective study in which the screening value of ADAM12 and PP13 for chromosomal abnormalities and adverse pregnancy outcome will be investigated.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Ear and labyrinthine disorders congenital
Study type	Observational invasive

Summary

ID

NL-OMON31468

Source
ToetsingOnline

Brief title
ADAM12 and PP13 in first trimester of pregnancy.

Condition

- Ear and labyrinthine disorders congenital
- Pregnancy, labour, delivery and postpartum conditions

Synonym
Down syndrome, Trisomy 21

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: ADAM12, Adverse pregnancy outcome, Down syndrome, PP13

Outcome measures

Primary outcome

The goal of this study is to determine differences in screening performance expressed as detection rate (DR), false positive rate (FPR) and odds of being affected given a positive result (OAPR). This will be analysed for the combined test with and without ADAM-12.

Secondary outcome

Attention will be given to the fact if ADAM12 and PP13 have predictive value for adverse pregnancy outcome.

Study description

Background summary

In the Netherlands prenatal screening for Down syndrome, trisomy 21, is currently performed with the first trimester combined test. This test is conducted between 8 and 13 weeks of pregnancy.
The risk calculation for Down syndrome is based on maternal age, ultrasound nuchal translucency measurement (NT) and maternal biochemical markers namely the free * subunit of hCG (fß-hCG) and pregnancy-associated plasma protein-A (PAPP-A), with a cut-off level of 1:200. To women with a screen positive result after prenatal screening a diagnostic test is offered. Prenatal diagnostic tests give certainty about the number of chromosomes of the foetus.

The predictive value of first trimester maternal serum markers for foetal chromosome abnormalities is well known. Whether these first trimester biochemical markers also have a predictive value of adverse pregnancy outcome,

intra-uterine foetal growth restriction, pregnancy induced hypertension or preterm delivery has not been very well investigated and does not have clinical importance yet.

ADAM stands for *a disintegrin and metalloprotease* is a metalloproteases and is produced by the placenta. A potential value of ADAM12 as an indicator of foetal chromosomal abnormalities has been suggested. It was shown that ADAM12 concentrations are reduced in cases with Down syndrome or other chromosomal abnormalities. Also a possible role for ADAM12 as predictor of preeclampsia and intra uterine foetal growth restriction (IUGR) is suggested.
Placental Protein 13 (PP13) is also produced by the placenta. Low PP13 concentrations are associated with abnormal implantation of the placenta. Therefore, PP13 seems to have potential value as screening marker for preeclampsia.

Study objective

The RIVM, UMCU and VUmc collectively will perform a prospective study in which the screening value of ADAM12 and PP13 for chromosomal abnormalities and adverse pregnancy outcome will be investigated.

Study design

Research goal is to include approximately 20,000 pregnancies in two years of study (singleton pregnancies only). The combined test will be conducted in the standard fashion.
Patients willing to participate in the ADAM12 /PP13 study will be asked to agree in having a second blood sample taken. The first sampling for free *-hCG and PAPP-A will be performed as early as possible (8-10 weeks of gestation). The second sampling is scheduled at the same day as the NT-measurement (12-13 weeks of gestation).
ADAM12 and PP13 concentrations will be additionally analysed for study objectives in both samples. In the study, the test results reported to the pregnant women are based on the current risk estimation. Pregnant women will not receive test results based on the ADAM-12/PP-13 concentrations. Pregnancy outcomes will be evaluated by questionnaire

Study burden and risks

The study will not bring any risk for the subjects.

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

Pregnant, singleton
Between 8-10 weeks gestation.

Exclusion criteria

Multiple pregnancies.
Gestation more than 10 weeks.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Start date (anticipated):	01-07-2008
Enrollment:	20000
Type:	Anticipated

Ethics review

Approved WMO

Date:	23-05-2008
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL17176.029.08