ADAM 12 en PP 13
Promising markers in the first trimester of pregnancy, concerning a elevated risk for Down syndrome and high risk pregnancies.

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1- To determine the physiological concentrations of ADAM12 and PP13, longitudinal, in the early first trimester in normal pregnancies. 2- To analyse the stability of these proteins, the effect of transport and higher temperatures.3- To compare the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON31549

Source
ToetsingOnline

Brief title
ADAM 12 and PP 13, promising pregnancy markers.

Condition

- Other condition
- Maternal complications of pregnancy

Synonym
pre-eclampsia, trisomy 21

Health condition

fysiologie bij de moeder tijdens de zwangerschap

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W,Rijksinstituut voor Volksgezondheid en milieu (RIVM)

Intervention

Keyword: ADAM 12, first trimester screening, physiology, PP 13

Outcome measures

Primary outcome

The concentrations of ADAM12 and PP13

The stability of ADAM12 and PP13

Secondary outcome

not relevant

Study description

Background summary

The first trimester combined test, to calculate the risk for Down syndrome is composed of the maternal serum concentrations pregnancy-associated plasma protein A (PAPP-A) and the free β subunit of human chorion gonadotrophin (fβhCG), combined with the measurement of the nuchal translucency (NT). There is a potential new marker, A Disintegrin And Metalloproteinase (ADAM12). ADAM12 is a glycoprotein which is synthesized by the placenta. The maternal serum concentrations of ADAM12 are reduced in Down syndrome and Edwards syndrome pregnancies. To make sure ADAM12 is a good screening parameter for the first trimester, we want to determine the normal physiological concentrations of ADAM12 during the first trimester.

Beside that there is another marker PP13. Placental Protein (PP13), a new maternal serum marker, shows potential for early detection of pre-eclampsia. Pre-eclampsia affects 2-7% of all pregnant women worldwide and is a major cause of maternal, fetal and neonatal morbidity and mortality. PP13 is a protein

expressed only in the placenta. It is involved in gluing the placenta to the uterus, and in remodelling the maternal arteries to expand them. Previous studies suggest that the gene for PP13 is down regulated in women with pre-eclampsia requiring that in pregnancies resulting in early pre-eclampsia there is impaired placental functional responsiveness to PP13 during the first trimester of pregnancy.

To determine the normal physiological concentrations of ADAM12 and PP13 during the first trimester, venous blood samples will be taken from 100 pregnant women at 6, 8, 10, 12 weeks of gestation and from 100 different pregnant women at 7, 9, 11, 13 weeks. The ADAM12 concentrations will be determined and the serum will be stored. From 50 women capillary blood samples will also be taken. These samples will be stored at 25 degrees and 40 degrees Celsius on filter paper (bloodspots) and in regular test tubes. The analysis of those concentrations will show the stability of ADAM12 and PP13 and any differences in ADAM12 and PP13 concentrations in venous vs. capillary blood.

Study objective

1- To determine the physiological concentrations of ADAM12 and PP13, longitudinal, in the early first trimester in normal pregnancies.

2- To analyse the stability of these proteins, the effect of transport and higher temperatures.

3- To compare the concentrations form the bloodspots vs venous blood.

4- Creating a serum-bank / data-bank from normal healty pregnancies, what can be used in the future to receive normal concentrations for new markers.

5- Compare the differences in concentrations of the markers between normal pregnancies and pregnancies after IVF, women with diabetes or pregnant women with a history of preterm labour, foetal growth restriction or pre-eclampsia.

6- To determine the relation between different levels of the serum markers and adverse outcome of the pregnancy.

Study design

observational study

Study burden and risks

Pregnant women visit the hospital 4 times, they undergo venous blood sampling and a short ultrasound examination of the mother. Venous blood sampling and

ultrasound examination is not associated with any risks.

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

First group: Normal singleton pregnancies, healthy women(200);Other groups: - Diabetic patients with singleton pregnancies (50), - IVF pregnancies (50), - pre-eclampsia or foetal growth restriction in a previous pregnancy (50)

Exclusion criteria

multiple pregnancies

fetus with chromosomal abnormalities (After finishing the study, the outcome is known. When the fetus has a chromosomal abnormality they will be exluded from the study.)

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-10-2008
Enrollment:	350
Type:	Actual

Ethics review

Approved WMO

Date:	18-02-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO

Date:	21-10-2008
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL16197.041.07