Dynamics of the human yolk sac in the first trimester of pregnancy.

Published: 10-04-2013
Last updated: 25-04-2024

To show that the human secondary yolk sac follows a dynamic pattern during the day by the investigation of:1.) size and volume of the human secondary yolk sac at several time points during one day2.) the relationship between size and volume of the...

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

Summary

ID

NL-OMON40049

Source
ToetsingOnline

Brief title
Yolk sac dynamics.

Condition

- Other condition

Synonym
fysiology of the human yolk sac in first trimester pregnancy / normal behavior of the yolk sac in early pregnancy

Health condition

geen aandoening; fysiologie van de dooierzak in het eerste trimester van de zwnagerschap

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: first trimester, glucose, pregnancy, yolk sac

Outcome measures

Primary outcome

Biometry of the yolk sac during the day (YSD, YSV) and blood glucose levels of the pregnant women preceding the ultrasound examinations. Time-dependent relationship, if any, between YS parameters (YSD and YSV) and blood glucose levels.

Secondary outcome

n.a.

Study description

Background summary

The variation in size and volume of the humane secondary yolk sac is large and an HbA1c related larger size of the yolk sac is found in diabetes type 1 patients. By measuring yolk sac parameters combined with blood glucose levels changes in yolk sac size and volume during the day can be detected.

Study objective

To show that the human secondary yolk sac follows a dynamic pattern during the day by the investigation of:
1.) size and volume of the human secondary yolk sac at several time points during one day
2.) the relationship between size and volume of the human secondary yolk sac and blood glucose levels

Study design

This study is a prospective, exploratory, follow-up study which will be embedded in the ongoing Predict study (METC Erasmus MC 2004-277), a hospital bases birth cohort study from preconception onwards at the Erasmus MC in Rotterdam. Predict study participants who volunteered for a longitudinal 3D ultrasound evaluation of early pregnancy will be included for another series of examinations.

We have an annual inclusion of 250 pregnancies in the Predict study. In approximately one year we will measure in 20 pregnancies, equally distributed over the gestational weeks 8-10, yolk sac size and volume five times during one day and as well determine blood glucose levels preceding these ultrasound examinations.

Intervention

Standardized breakfast.

Study burden and risks

The women who volunteered for the ultrasound scans in the first trimester are asked to visit the Erasmus MC for four extra ultrasound scans during one morning. The regular weekly visit of the Predict study will also be performed this morning; ending up with five measurement moments. These four extra ultrasound scans will take about 15 minutes per scan. The first scan will be performed at 8:00 a.m. after determing a fasting glucose and is followed by a standardized breakfast. Then every hour an ultrasound scan is performed until 12:00 p.m. preceded by a determination of blood glucose levels. The techniques that we will be used are safe and harmless. The patients will receive a picture of their unborn child obtained by 3D ultrasound.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

's-Gravendijkwal 230
Rotterdam 3015 CE
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

's-Gravendijkwal 230
Rotterdam 3015 CE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Predict study participants who volunteered for a longitudinal 3D ultrasound evaluation in early pregnancy and who were willing to volunteer for one additional series of four ultrasound scans and for five additional determinations of blood glucose levels preceding the extra ultrasound scans. Their gestational age has to be in the range of 7+4 to 10+3 weeks based on last menstrual period or conception date.

Exclusion criteria

- Women < 18 years of age
- A gestational age of < 7+4 or > 10+3 weeks
- Clinically unstable women
- Clinically unstable fetuses
- Women with diabetus mellitus
- Multiple pregnancy

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-08-2013
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	10-04-2013
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	NL42414.078.12