The fetal face, a two- and threedimensional ultrasonographic evaluation, nomograms and maternal attachment

Published: 10-11-2006
Last updated: 21-05-2024

The primary objective of this study is: * to provide baseline normative data of the fetal face. The secondary objectives of the study are: * to compare two-dimensional ultrasound with three-dimensional ultrasound in evaluating the fetal face. * to...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neonatal and perinatal conditions
Study type	Observational non invasive

Summary

ID

NL-OMON30025

Source
ToetsingOnline

Brief title
Fetal face

Condition

- Neonatal and perinatal conditions

Synonym
congenital facial anomaly, genetic facial anomaly

Research involving
Human

Sponsors and support

Primary sponsor: St. Antonius Ziekenhuis

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: fetal face, prenatal diagnosis., ultrasound

Outcome measures

Primary outcome

Of 300 volunteers about 20 measurements of the fetal face will be taken with

two- and three-dimensional ultrasound.

Secondary outcome

A set of two MAAS-questionnaires of the volunteers participating in the study

will be collected.

Study description

Background summary

Facial anomalies are part of many syndromes and chromosomal disorders.
The prenatal recognition of a facial anomaly and the possible presents of a genetic syndrome or chromosomal disorder can change obstetrical management and neonatal care.
Morphological standards that describe the fetal face are very rare.
Three-dimensional ultrasound is seen as a potential new instrument to clarify facial anatomy and consequently diagnose anomalies. Objective normative data of the fetal face will provide standards for classification, comparison, documentation and communication and may facilitate early diagnosis of malformation syndromes. Ultimately this will assist the physician to provide the parents with adequate counseling regarding prognosis, treatment options, preventative care, pathogenesis and recurrence risk.

Study objective

The primary objective of this study is:
* to provide baseline normative data of the fetal face.

The secondary objectives of the study are:
* to compare two-dimensional ultrasound with three-dimensional ultrasound

in
evaluating the fetal face.
* to explore the effect of three-dimensional ultrasound of the fetal face
on
maternal bonding.

Study design

The study will be a prospective observational non-invasive study.

Study burden and risks

Nature and extent of the burden:
About 300 volunteers will participate one time for an abdominal ultrasound examination of 30 minutes (transsectionally). They will be asked to fill in the MAAS questionnaire one week before the ultrasound and two weeks after the ultrasound. This will take about 5 minutes each time. They will also be asked to send a return form after birth. This will take about 2 minutes.
About 30 volunteers will participate 6 times for an ultrasound examination of about 15 minutes (longitudinallly). They will be asked to fill in the MAAS questionnaire one week before the first ultrasound and two week after the last ultrasound. They will also be asked to send a return form after birth.

Risks associated with participation:
There are no health risks associated with two-or three dimensional ultrasound.

Benefit:
By participating in the fetal face project the volunteers have an extra possibility to look at there unborn child with ultrasound.

Group relatedness:
Only healthy pregnant Caucasian women are included.

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

Healthy Caucasian prenant women with a singleton pregnancy.

Exclusion criteria

-no Caucasian father
-growth below the 5th percentile
-growth above the 95th percentile
-congenital anomaly

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-11-2006
Enrollment:	330
Type:	Actual

Ethics review

Approved WMO

Date:	10-11-2006
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL12414.100.06