Volumetry during the first trimester of the pregnancy using three-dimensional ultrasonography

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Understanding the normal development of the early pregnancy and observing this process ultrasonographically has allowed us to monitor effectively first trimester pregnancy, and recognize early signs of abnormal outcome. The CRL (Crown-Rump-Length)…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Pregnancy, labour, delivery and postpartum conditions
Study type	Observational non invasive

Summary

ID

NL-OMON30465

Source
ToetsingOnline

Brief title
volumetry using three-dimensional ultrasonography

Condition

- Pregnancy, labour, delivery and postpartum conditions

Synonym
illness during pregnancy, pregnancy related disorders

Research involving
Human

Sponsors and support

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

Intervention

Keyword: volumetry trimester three-dimensional ultrasonography

Outcome measures

Primary outcome

The primary objective of this study is to measure the volume of the fetus at

11-13 weeks of gestation and calculating the normal values with the secundairy

objective to diagnose pregnancy related complications earlier.

This volume is obtained using 3DUS in singleton pregnancies undergoing the NT

measurement. By calculating the normal curve we will make allowance for age and

length of the parents, ethnicity and intoxications. The found volumina will

becombined to the outcome of the pregnancy.

Secondary outcome

Study description

Background summary

Classic human embryology was established by Wilhelm His in 1880-85. His realized the need for magnified three-dimensional (3D) imaging and the need for a model of the fetal anatomy.
Nowadays ultrasonography has a very important role in practical embryology and it can not be missed in practice anymore. The development of computer technology has opened new possibilities for 3D reconstructions. The first attempt at constructing 3D images of fetus from ultrasound recordings was made in the early 1980s by Brinkley et al. The first volumetric evaluation using 3-D ultrasonopgraphy(US) to predict fetal loss during the first trimester was performed by Steiner et al in 1994. Since a few years very specific ultrasonogrpaphic volumetry measurements have become possible. This technique combines the possibilities of ultrasonography and x-ray computed tomography(CT) and is similar to 3D CT and magnetic resonance imaging both in principle and in terms of the method of image creation. Due to this technique it is possible to

provide more data about the development of the pregnancy.
Authors of numerous large and small studies report the benefits of adding 3D ultrasonography to the already well-established 2D ultrasonography to improve the accuracy of prenatal diagnosis. 3D US takes less time, is more authomated and less operator-dependent as 2D US.
In vitro studies demonstrated that 3DUS is superior to 2DUS for volumetric measuring of objects with irregular shapes. With its reproducibility in vivo being recently proved.
The aim of this study is to gain the normality curve of the volume of the fetus using transabdominal and transvaginal 3DUS at 11+0 to 13+6 weeks of gestation.
Volumetric calculation by rotation has become possible through the introduction of the VOCAL imaging program, an extension of 3D View (GE Kretz, ZIpf, Autria).
By measuring the normality curve we suggest that we can prove the diagnose of pregnancy related disorders more early in the pregnancy by using this 3DUS technique and the volumetric measurements. These anomalies are now diagnosed later. It could be congenital anomalies or pregnancy related complications.

Study objective

Understanding the normal development of the early pregnancy and observing this process ultrasonographically has allowed us to monitor effectively first trimester pregnancy, and recognize early signs of abnormal outcome.
The CRL (Crown-Rump-Length) is seen as the most accurate method to determine the gestational age and in some cases also the pregnancy outcome.
We suggest that 3D ultrasonogrpahic volumetric measurements during the first trimester will have a important surplus value at preterm diagnosis of congenital anomalies or pregnancy related disorders.
The primary objective of this study is to measure the volume of the fetus at 11-13 weeks of gestation and calculating the normal values with the secundairy objective to diagnose pregnancy related complications earlier.
This volume is obtained using 3DUS in singleton pregnancies undergoing the nuchal translucency (NT) measurement.
By calculating the normal curve we will make allowance for age and length of the parents, ethnicity and intoxications. The found volumina will be combined to the outcome of the pregnancy.

Study design

This is a prospective cohort study accomplished in the Máxima Medical Centre Veldhoven, the Netherlands with a duration of 13 months.

Study burden and risks

Ultrasound is already used for over more than 30 years. Untill now no unprofitable effects are reported in practice and extensive scientific research for mother as fetus.

The cooperating patients will not get an different treatment as the not cooperating patients. But the not-cooperative patients will not get a 3DUS examination.
This ultrasonogrphic examination will take about 30 minutes. Because of the supplementary 3DUS it can take a few minutes more.

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

single gestation
certain gestational age of 11-13 weeks

Exclusion criteria

twin gestation
uncertain gestational age

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):	01-09-2007
Enrollment:	500
Type:	Actual

Ethics review

Approved WMO

Date:	10-07-2007
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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	NL15733.015.07