Three-dimensional ultrasound of the cervix during midpregnancy screening ultrasound

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-Comparing two-dimensional and three-dimensional ultrasound length measurement-Evaluate improvement in three dimensional ultrasound imaging. Assessing possibility of cervical volume measuring.-Assessing intra- and inter-observer variation of...

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

Summary

ID

NL-OMON32668

Source
ToetsingOnline

Brief title
Three-dimensional ultrasound of the cervix

Condition

- Pregnancy, labour, delivery and postpartum conditions

Synonym
preterm labour, short cervix

Research involving
Human

Sponsors and support

Primary sponsor: Atrium Medisch Centrum
Source(s) of monetary or material Support: Geen;eigen inzet

Intervention

Keyword: Cervix, Pregnancy, Three-dimensional, Ultrasound

Outcome measures

Primary outcome

Cervical volume

Cervical length

Secondary outcome

Inter and intra-observer variation

Average values of cervical volume in 20 weeks of ammenorrhoea

Study description

Background summary

Preterm delivery is major health issue and is one of the main reasons of perinatal mortality. The incidence is about 5 * 8 % and seems to be rising in developed countries. This all is a burden on general health care. Previous research showed that a shortened cervical length in late second trimester or early third trimester is related to a higher risk on preterm delivery. The earlier the shortened cervical length and the shorter the cervical length, the higher the risk. The cervical length is measured by a two-dimensional trans-vaginal ultrasound. Due to anatomical features of the cervix and limitation by a two-dimensional view, the length measured by a two-dimensional is not perfect and measuring errors do occur. This results in both over and under-estimation of the cervical length. A recent review reports that two-dimensional ultrasound of the cervix is not applicable as a screening instrument.
Untill now, there is no evidenced based protocol for risk management in case of a shortened cervical length. In the Netherlands, this is a research topic in the national TRIPLE P consortium study.
Several years ago, three dimensional ultrasound was introduced. Since introduction of this technique, measuring of a volume is possible. Great advantage of this three-dimensional technique is the additional coronal view

The most recent report on three dimensional measured cervical volume date from 2006, using imaging dating from 2004.

Measuring cervical volume is promising due to the assumption that small alterations in cervical length result in bigger changes in cervical volume. Until recently, three dimensional had is technical limitations due to little contrast between cervix and surrounding tissues. Research showed variable results in diagnostic power of three dimensional ultrasound. These limitations are most likely discarded by technical improvement, allowing a better risk assessment. This, combined with more and better treatment options hopefully leads to a drop in the incidence of perinatal mortality.

Study objective

-Comparing two-dimensional and three-dimensional ultrasound length measurement
-Evaluate improvement in three dimensional ultrasound imaging. Assessing possibility of cervical volume measuring.
-Assessing intra- and inter-observer variation of cervical volume measruments
-Assessing average value of cervical volume at 18-20 weeks of ammenorrhoea

Study design

Prospective cohort study

Study burden and risks

The patients will be included after informed consent for both transvaginal ultrasound and data collection about pregnancy outcome. No questionnairs will be used.

Extensive medical research has shown that there are no risk of negative side-effects of ultrasound on pregnant women and the unborn child.

The extra-burden for the patients consist of, additional to a abdominal ultrasound, a transvaginal ultrasound. This additional ultrasound will cost an extra 5 minutes. Pain is very rare during transvaginal ultrasound.

The patient will have no direct substantial benefit from participating in this study. Benefit will consist of better diagnostic tools in the future.

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

Gestational age of 18-22wks

Exclusion criteria

< 18years of age
no comprehension of the patient information form

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):	12-01-2010
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	25-11-2009
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL29776.096.09