First trimester fetal movements using 4D ultrasound and Virtual Reality: a pilot study.

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A new method, implemented in the I-Space Virtual Reality application, will be tested on its reproducibility and validity. It will be used to describe fetal movement patterns. This new method can improve the rapidity of fetal movement studies and...

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

Summary

ID

NL-OMON42679

Source
ToetsingOnline

Brief title
Fetal movements in early pregnancy.

Condition

- Other condition

Synonym
fetal movement, neurologic development

Health condition

Zwangerschap - ontwikkeling van beweging bij de foetus

Research involving
Fetus in utero

Sponsors and support

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

Intervention

Keyword: 4D ultrasound, Fetal movements, First trimester pregnancy, Virtual reality

Outcome measures

Primary outcome

This is a pilot study to investigate the validity and reproducibility of our newly introduced automated movement measuring method using 4D ultrasound and Virtual Reality. The reproducibility and validity of the newly introduced movement measuring method in Virtual Reality will be studied.

Secondary outcome

Movement patterns will be described using volume automated replacement techniques. Movements will be described and analyzed: type of movements (qualitative), movement patterns (including angle of movement, amount of movement = quantitative), time that fetuses move compared to resting moments. Movement patterns will be compared to movement patterns described in other studies using 2D ultrasound.

Study description

Background summary

Optimal embryonic development is of crucial importance throughout life. At 9 weeks gestational age more complex movements appear, in which all body parts participate. Until now two-dimensional (2D) and three-dimensional (3D) vaginal and abdominal ultrasound data are used to study early fetal movement patterns. The I-Space Virtual Reality application allows depth perception and real 3D and

four-dimensional (4D) visualization. Movement patterns can be analyzed easier and in more detail, with this method. Secondary, the analysis of the movements will be faster using a new method of analysis.

Study objective

A new method, implemented in the I-Space Virtual Reality application, will be tested on its reproducibility and validity. It will be used to describe fetal movement patterns. This new method can improve the rapidity of fetal movement studies and allows to study the movement patterns in more detail. Normal fetal movement patterns will be described.

Study design

This will be a prospective observational pilot study.

Study burden and risks

One 4D vaginal ultrasound will be performed at 10 weeks of gestation. The total transvaginal scanning time will be kept as short as possible (maximum of 30 minutes) and will follow ISUOG recommendations (2013). No additional risks are to be expected from this ultrasound examination.

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 pregnant woman who conceived spontaneously from a singleton pregnancy.
- Age * 18 years.
- Gestational age of 10 weeks, confirmed by CRL measurement earlier in pregnancy.
- Sufficient knowledge of the Dutch language.
- Signed informed consent.

Exclusion criteria

- Unknown or uncertain gestational age.
- Pregnancy with overt congenital abnormalities.
- Multiple pregnancy.
- High risk pregnancy.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped

Start date (anticipated):	23-12-2015
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	01-12-2015
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	NL54526.078.15