Het nut van driedimensionale virtual reality echoscopie tijdens de eerste drie maanden van de zwangerschap

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28245

Source
NTR

Brief title
VIRTUAL REALITY FETUS STUDY

Health condition

Women with a first trimester pregnancy at risk for a child with a congenital anomaly (=i.e. a high risk pregnancy). A high risk pregnancy means that there is an increased risk of the development of an anomaly in any of the fetal organ systems; for example the brain, skull, face, abdominal wall, thorax, extremities, skeleton, heart, neural tube, kidneys, placenta, amniotic fluid, umbilical cord and an increased thickness of the nuchal fold, when compared to the general population.

Key words: 3D ultrasound, virtual reality, first trimester anomaly scan

Sponsors and support

Primary sponsor: Department of Obstetrics and Gynaecology
Division of Obstetrics and Prenatal Medicine
Erasmus MC University Medical Centre Rotterdam
Source(s) of monetary or material Support: Erasmus MC Mrace Efficiency Research

Intervention

Outcome measures

Primary outcome

Detection rates of congenital anomalies when 3D VR is used in the first trimester compared to 2D ultrasound examination in the second trimester of pregnancy when applied in a high risk population.

Secondary outcome

Secondary parameters:
- Health related quality of life (physical, mental, emotional and social functioning) in terms of QALY’s (maternal perspective).

- Cost-effectiveness (costs per detected anomaly from a societal perspective).

Tertiary parameters:

- Patient and clinician satisfaction.

Study description

Background summary

Rationale: A considerable amount of fetal anomalies can already be detected by ultrasound by the end of the first trimester. Within the Erasmus MC, a new technique has been developed, using virtual reality (VR) displays, enabling three dimensional (3D) depth perception and interaction. This new system provides a validated and reliable method for measuring embryonic development and can be used in daily outpatient practice. It is assumed that 3D VR in the first trimester has a diagnostic accuracy comparable to the two dimensional (2D) scan in the second trimester. 3D VR might be of additional value in the detection of anomalies in case of a comparable diagnostic accuracy to the golden standard. This may result in an improvement of the health related quality of life and adjustment of treatment strategies.

Objective: To investigate whether 3D VR ultrasound is of additional value in the detection of fetal anomalies in the first trimester when compared to the 2D ultrasound scan in the second trimester of pregnancy (=usual care) within a high risk population. Moreover, it will be investigated whether the results of the 3D VR first trimester scan are of value in terms of

diagnostic accuracy. Additionally, it needs to be clear whether the use of 3D VR ultrasound is of benefit for the pregnant population with respect to psychological burden/stress and treatment options (health-related quality of life). Finally, cost-effectiveness (in terms of health gain) of this new diagnostic modality will be evaluated (societal perspective).

Study design: Randomized controlled trial.

Study population:

Women with a first trimester pregnancy at risk for a child with a congenital anomaly (=i.e. a high risk pregnancy). A high risk pregnancy means that there is an increased risk of the development of an anomaly in any of the fetal organ systems; for example the brain, skull, face, abdominal wall, thorax, extremities, skeleton, heart, neural tube, kidneys, placenta, amniotic fluid, umbilical cord and an increased thickness of the nuchal fold, when compared to the general population.

Intervention:

First trimester 3D VR ultrasound examination versus second trimester 2D ultrasound examination. The intervention group will undergo an additional 2D and 3D examination between 11+0 and 13+6 weeks gestational age (GA) using a high-resolution transvaginal or abdominal probe on a regular ultrasound machine (Voluson E10, GE Healthcare). This intervention will take 30-45 minutes. Firstly, an extensive examination and evaluation of all organ systems will be performed using 2D ultrasound. At the same time various 3D ultrasound datasets will be generated; including all organ systems of the fetus. This examination will be performed by examiner A (Flow chart ultrasound examinations, Appendix A). The 3D datasets will be transferred to the desktop VR system, using a 3D monitor and a tracking system together with the V-Scope software. V-Scope is a volume rendering application, especially developed for the VR visualization of medical volumetric data, such as 3D ultrasound. In the presence of the future parents, the whole fetus will be checked by an independent and blinded examiner B on congenital anomalies using the standardized list (Protocol fetal medicine scan, Appendix B). This examination will take an additional 30 minutes.

The control group will undergo a second trimester (18+0-22+6 weeks GA) 2D ultrasound examination according to the standardized protocol (Protocol fetal medicine scan, Appendix B). After each ultrasound examination, parents will fill out a validated questionnaire about their health-related quality of life (HRQoL) (SF36 questionnaire, Appendix C), a specific questionnaire about fear and depression (Hospital Anxiety and Depression Scale (HADS),

Appendix D) and an evaluation of a general fear related questionnaire (State Trait Anxiety Inventory, Appendix E; Thermometer, Appendix F). The outcomes will be compared between the intervention and the usual care group. Additionally, women who undergo the 3D VR scan will fill out a questionnaire with respect to their experience with the 3D VR ultrasound technique (applicability, feasibility, and satisfaction; the 3D VR questionnaire: Questionnaires Patient Satisfaction for the intervention group, Appendix G). Another version of the 3D VR questionnaire will be filled out by investigators performing these examinations (Questionnaire Clinician Satisfaction, Appendix H). Women who do not undergo the 3D VR scan, will also fill out a similar questionnaire with respect to their experience not having the opportunity to undergo an extensive first trimester ultrasound examination (Questionnaires Patient Satisfaction for the control group, Appendix I). Finally, costs of the two treatment regimens will be compared (Cost analysis protocol, Appendix J) for which all participants fill in a Medical Consumption Questionnaire (MCQ) twice (Appendix K). In Appendix L, a flowchart outlining the whole study protocol is included. At the end of the study, health care workers will be interviewed about their overall experience of the newly introduced scan (3D VR ultrasound); which will be qualitative interviews. These interviews will take around 30 minutes, depending on the response of the health care workers (Interview Clinician Satisfaction, Appendix M).

Main study parameters/endpoints:

Detection rates of congenital anomalies when 3D VR is used in the first trimester of pregnancy and compared to 2D ultrasound examination in the second trimester of pregnancy. The golden standard will be the clinical investigation of the neonate (including the information provided by pathological examination). Additionally, the efficacy of the first trimester 3D VR ultrasound examination will be studied (including the detection rates, HRQoL, cost-effectiveness and patient satisfaction).

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

Patients in the 3D VR ultrasound group, will pay one extra visit between 11+0 and 13+6 weeks GA to undergo a transvaginal or transabdominal ultrasound examination. This examination will take around 30-45 minutes. All participants will fill in various questionnaires. The SF36, HADS, STAI questionnaires and the Thermometer tool will be filled out at different time points (Appendix L). The newly developed questionnaire will be filled out at the same time period. Additionally, twice all participants will fill in a list (MCQ) with all the medical expenses they have made.

The study is a diagnostic study. Based on the information provided by this study, patients can even opt to terminate their pregnancy. This is not different from clinical standard care.

Study objective

To investigate whether 3D VR ultrasound is of additional value in the detection of fetal anomalies in the first trimester when compared to the 2D ultrasound scan in the second trimester of pregnancy (=usual care) within a high risk population. Moreover, it will be investigated whether the results of the 3D VR first trimester scan are of value in terms of diagnostic accuracy. Additionally, it needs to be clear whether the use of 3D VR ultrasound is of benefit for the pregnant population with respect to psychological burden/stress and treatment options (health-related quality of life). Finally, cost-effectiveness (in terms of health gain) of this new diagnostic modality will be evaluated (societal perspective).

Study design

Not applicable. We expect to include 1000 participants annually.

Intervention

First trimester 3D VR ultrasound examination versus second trimester 2D ultrasound examination. The intervention group will undergo an additional 2D and 3D examination between 11+0 and 13+6 weeks gestational age (GA) using a high-resolution transvaginal or abdominal probe on a regular ultrasound machine (Voluson E10, GE Healthcare). This intervention will take 30-45 minutes. Firstly, an extensive examination and evaluation of all organ systems will be performed using 2D ultrasound. At the same time various 3D ultrasound datasets will be generated; including all organ systems of the fetus. This examination will be performed by examiner A (Flow chart ultrasound examinations, Appendix A). The 3D datasets will be transferred to the desktop VR system, using a 3D monitor and a tracking system together with the V-Scope software. V-Scope is a volume rendering application, especially developed for the VR visualization of medical volumetric data, such as 3D ultrasound. In the presence of the future parents, the whole fetus will be checked by an independent and blinded examiner B on congenital anomalies using the standardized list (Protocol fetal medicine scan, Appendix B). This examination will take an additional 30 minutes.

Contacts

Public
PO Box 2040
A Mulders
Erasmus MC Medical Center, Department of Obstetrics and Gynaecology, University Medical Centre Rotterdam, Division of Obstetrics and Prenatal Medicine Erasmus MC. SK Sp-4457
Rotterdam 3000 CA
The Netherlands
+31 10 703 3492
Scientific
PO Box 2040
A Mulders

Erasmus MC Medical Center, Department of Obstetrics and Gynaecology, University Medical Centre Rotterdam, Division of Obstetrics and Prenatal Medicine Erasmus MC. SK Sp-4457
Rotterdam 3000 CA
The Netherlands
+31 10 703 3492

Eligibility criteria

Inclusion criteria

- Women age 18 or above.

- Viable pregnancy, including multiple pregnancies.

- Sufficient understanding of the Dutch language (written and spoken).

- Referred to the department of Prenatal Diagnosis in the first trimester of pregnancy because of a high risk of having a fetus with an anomaly (=i.e. the high risk population).

Exclusion criteria

- Women under 18 years of age.

- Non-viable pregnancy.

- No sufficient understanding of the Dutch language.

- Detection of an anomaly in the current pregnancy before randomization.

- In case of pregnancy duration > 13+6 weeks.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2017
Enrollment:	2800
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Plan description
The trial data will not become publicly available but will be available upon reasonable request to the corresponding author.

Ethics review

Positive opinion

Date:	26-01-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 50508
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6162
NTR-old	NTR6309
CCMO	NL58563.078.16
OMON	NL-OMON50508

Study results

Summary results

Pietersma, C.S., Mulders, A.G.M.G.J., Moolenaar, L.M. et al. First trimester anomaly scan using virtual reality (VR FETUS study): study protocol for a randomized clinical trial. BMC Pregnancy Childbirth 20, 515 (2020). https://doi.org/10.1186/s12884-020-03180-8