# Virtual Reality & Feasibility and Efficacy of first Trimester Ultrasound: a randomized controlled trial.

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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....

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

## Summary

### ID

NL-OMON50508

**Source**
ToetsingOnline

**Brief title**
Virtual Reality FETUS study

### Condition

- Pregnancy, labour, delivery and postpartum conditions

**Synonym**
Congenital anomalies

**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:** Feasibility and efficacy, First trimester, Ultrasound, Virtual reality

## 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. Follow-up data (pregnancy outcome) will be collected (which is currently standard care) together with the clinical investigation of the neonate (post mortem examination = *Golden Standard*).

### Secondary outcome

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).

# Study description

### Background summary

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 as the golden standard. This may result in an improvement of the health related quality of life and adjustment of treatment strategies.

### 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 (health care perspective as well as societal perspective).

### Study design

Multicentre, randomized controlled trial.

### Study burden and risks

Patients who are in the 3D VR ultrasound arm, will pay one extra visit to the department of Prenatal Diagnosis of the Erasmus MC 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, 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, all participants will fill in a list (MCQ) with all the medical expenses they make twice.
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.

## Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

## Inclusion criteria

- Women above 18 years of age.
- Viable pregnancy, including multiple pregnancies.
- Sufficient understanding of the Dutch language (written and spoken).
- Pregnant women in the first trimester of pregnancy with a high risk of having a fetus with an anomaly (<= 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

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| Study type: | Observational non invasive |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |

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| Control: | Active |
| Primary purpose: | Diagnostic |

### Recruitment

NL

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| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 06-07-2017 |
| Enrollment: | 2810 |
| Type: | Actual |

## Ethics review

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| Approved WMO Date: | 16-01-2017 |
| Application type: | First submission |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 12-12-2019 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 20-12-2019 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 09-04-2020 |
| Application type: | Amendment |
| 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

ID: 28245
Source: Nationaal Trial Register
Title:

## In other registers

| Register | ID |
|---|---|
| CCMO | NL58563.078.16 |
| OMON | NL-OMON28245 |