Abdominale MRI tijdens zwangerschap

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28141

Source
Nationaal Trial Register

Brief title
N/A

Health condition

N/A

Sponsors and support

Primary sponsor: MMC
Source(s) of monetary or material Support: Not applicable

Intervention

Outcome measures

Primary outcome

Producing 3D replicas of the pelvis, the uterus including placenta, amniotic fluid and child, the pelvic floor and the birth canal of the pregnant woman by using already made and existing MRIs.

Secondary outcome

The 3D replicas should help in the evaluation how we might design a procedure and device

for the AW that will allow medical professionals to successfully transfer a premature baby from the vaginal birth canal into the artificial uterus without causing unnecessary physical or psychological damage.

Study description

Background summary

To improve the outcomes for extreme preterm infants, the Perinatal Life Support (PLS) consortium is developing a medical device - an artificial womb (AW) - that supports the growth of this extremely premature group better and safer outside the uterus. Rather than exposing the preterm child to the stressful treatments of the NICU, the AW retains the liquid environment of the natural uterus. In order to ensure that the transfer of the premature child runs as smoothly as possible, a device with artificial amniotic fluid is developed to accommodate the premature child during a vaginal birth. The child will be placed in the AW from this “collection bag”. In order to develop a device that optimally matches the birth canal of the mother during delivery, we want to produce realistic replicas of the uterus, placenta, fetus in the uterus, pelvic floor and birth canal. In this retrospective study we will be using existing MRI images of pregnant women, in order to model these anatomical parts in 3D software.

Study objective

This is a retrospective study to make use of existing MRIs made from pregnant women who suspected a complication after bariatric surgery in pregnancy to make 3D replicas.

Study design

The patients will be contacted by the coordinating investigator and in case of consent these patients will be sent a PIF.

Intervention

No interventions, study is retrospective.

Contacts

Public
Eindhoven University of Technology
Juliette van Haren

0624989000
Scientific
Eindhoven University of Technology
Juliette van Haren

0624989000

Eligibility criteria

Inclusion criteria

- MRI is made at an amenorrhea period of 20-30 weeks.
- Pregnant patients suspected of having a complication after bariatric surgery and who have had an MRI.

Exclusion criteria

- Major anatomical abnormalities of the fetus and birth canal.
- Placenta previa.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	28-05-2020
Enrollment:	24

Type: Anticipated

IPD sharing statement

Plan to share IPD: No

Plan description
N/A

Ethics review

Not applicable
Application type: Not applicable

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
NTR-new	NL8681
Other	METC MMC : TBD

Study results

Summary results
N/A