Bariatric surgery and EmbrYONic Development

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To assess embryonic, foetal and placental growth trajectories by serial assessments of sizes and volumes and foetal morphology during the first, second and third trimester of pregnancy with the aim to examine whether BS influences embryonic growth...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Congenital and hereditary disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON48200

Source
ToetsingOnline

Brief title
BEYOND study

Condition

- Congenital and hereditary disorders NEC
- Pregnancy, labour, delivery and postpartum conditions

Synonym
embryonic development, Weight-loss surgery

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Bariatric, Development, Embryonic, Surgery

Outcome measures

Primary outcome

The relationship between bariatric surgery and embryonic growth measured by embryonic volume offline on 3D ultrasound scans and Virtual Reality-techniques.

Secondary outcome

The relationship between bariatric surgery and:

a) Maternal biomarkers such as vitamin status (blood)

b) Vaginal and faecal microbiome

c) (Pre)clinical maternal outcomes (e.g. pregnancy outcome, preeclampsia, gestational diabetes)

d) (Pre)clinical embryonic/foetal outcomes (e.g. growth trajectories in the first, second and third trimester, miscarriage, birth weight)

e) Maternal conditions and lifestyle (e.g. medication use, intoxications, infections, physical activity, working activities, body mass index (BMI), blood pressure, nutrition, smoking, alcohol, folic acid supplement use, vitamin supplement use)

f) Placental development

Study description

Background summary

The worldwide obesity epidemic has resulted in more frequent bariatric surgery (BS) in women of reproductive age over the past decades. Maternal health in the

periconception period is crucial for embryonic and foetal development. BS can lead to maternal vitamin deficiencies, a change in maternal lifestyle and possibly an increased risk of prematurity and foetal growth restriction, thereby also affecting health in later life for both the future mother and her offspring. Foetal growth and volume, as well as placental growth and diverse foetal structures can be measured by ultrasound techniques.

Study objective

To assess embryonic, foetal and placental growth trajectories by serial assessments of sizes and volumes and foetal morphology during the first, second and third trimester of pregnancy with the aim to examine whether BS influences embryonic growth compared to women who have not undergone BS.
Furthermore, we want to explore whether BS influences foetal and placental growth compared to women who have not undergone BS.
Moreover, we want to explore the relationship between BS and periconception maternal lifestyle, health and vitamin status, and the influence of these determinants on embryonic, foetal and placental development.

Study design

This study will initially start with creating an overview of health status based on retrospective medical record review concerning health status of both pre- and postbariatric surgery status as well as pre- and postconceptional status. A prospective, observational cohort study will be performed embedded within the Rotterdam Periconception cohort (Predict study), a hospital-based birth cohort study from preconception onwards.

Study burden and risks

For all cases the risks involve primarily the burden of participating in a study, which usually means additional hospital visits and assessments. There will be a maximum of 6 hospital visits, which will take approximately 30-45 minutes each. There will be three first trimester vaginal ultrasound examinations (as part of the Predict study, METC 2004-227) and one abdominal ultrasound examination during both second and third trimester. At 4 of the appointments (preconceptionally and in the first, second and third trimester) blood will be taken and vaginal and faecal swabs will be taken by the patients themselves. The weight, height and blood pressure of the male partners will be measured (preconceptionally and during the first trimester) and blood will be taken from the male partner at 1 appointment (in the first trimester). The risks of participation are considered to be minor and the potential benefit outweighs the risks. From the above, it is clear that there are no obvious risks associated with participation in the study. After each visit, the patient will receive a picture of their child obtained by 3D or 2D ultrasound. The controls have already been included and do not undergo any extra measurements

pertaining to the BEYOND study.

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

Cases (women)
1) Women >= 18 and 45 <= years of age, <12 weeks pregnant of a singleton pregnancy.
2) Understanding of Dutch in speaking and reading.
3) Willingness to give written informed consent.
4) Having undergone bariatric surgery prior to inclusion (any type of bariatric surgery is included, except for having undergone a gastric banding procedure that has been deflated or removed).

Cases (men):
1) Partner of a woman who is eligible for inclusion.
2) Understanding of Dutch in speaking and reading.
3) Willingness to give written informed consent.

Controls (women)
1) Women >= 18 and 45 <= years of age, <12 weeks pregnant of a singleton pregnancy.
2) Understanding of Dutch in speaking and reading.
3) Willingness to give written informed consent.
4) Having undergone bariatric surgery prior to inclusion.
5) Has participated in the Predict study.

Controls (men)
1) Partner of a woman who is eligible for inclusion.
2) Understanding of Dutch in speaking and reading.
3) Willingness to give written informed consent.
4) Has participated in the Predict study.

Exclusion criteria

1) Unable or unwilling to give informed consent.
2) Multiple pregnancy.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-03-2020

Enrollment:	190
Type:	Actual

Ethics review

Approved WMO Date:	05-11-2019
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	08-12-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	12-04-2021
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

No registrations found.

In other registers

Register	ID
CCMO	NL71108.078.19