BEYOND- Bariatrics and EmbrYONic Development: The influence of bariatric surgery on maternal periconception health, embryonic growth and fetal development.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24076

Source
Nationaal Trial Register

Brief title
BEYOND

Health condition

Obesity

Sponsors and support

Primary sponsor: Erasmus MC, University Medical Center Rotterdam
Source(s) of monetary or material Support: Erasmuc MC, Obstetrics and Gynaecology

Intervention

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.
We hypothesize that BS impairs embryonic growth and leads to more vitamin deficiencies before and during pregnancy.

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. At four moments women will undergo blood measurements and at three moments women will undergo ultrasound examination and

With this study we aim to provide:
1) More knowledge about 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. 2) Information about whether BS influences embryonic growth compared to women who have not undergone BS.
3) Whether BS influences foetal and placental growth compared to women who have not undergone BS 4) More insights into 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 objective

Bariatric surgery leads to vitamin deficiencies and a malabsorptive state that impairs embryonic growth.

Study design

- Preconceptional (maximum one year before conception)
- First trimester
- Second trimester
- Third trimester

Intervention

- Transvaginal ultrasound (preconceptional and in the first trimester)
- Transabdominal ultrasound (in the second and third trimester)
- Biomarkers

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a case must meet all of the following criteria:
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)

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.

In order to be eligible to participate in this study, a control must meet all of the following criteria:
Women
1) ≥18 and 45 ≤ years of age, <12 weeks pregnant of a singleton pregnancy.
2) Understanding of Dutch (Erasmus MC) in speaking and reading.
3) Willingness to give written informed consent.
4) Not having undergone bariatric surgery prior to inclusion.
5) Participant in the PREDICT study

Men:
1) Partner of a woman who is eligible as a control
2) ≥18 and 45 ≤ years of age
3) Understanding of Dutch (Erasmus MC) in speaking and reading.
4) Willingness to give written informed consent.
5) Participant in the PREDICT study

Exclusion criteria

A potential case or control who meets any of the following criteria will be excluded from participation in this study:
1) Unable or unwilling to give informed consent.
2) Multiple pregnancy.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial

Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	05-01-2020
Enrollment:	190
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	05-12-2019
Application type:	First submission

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	NL8217
CCMO	NL OZBS72.19167

Study results