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

Gepubliceerd: 05-12-2019 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24076

Bron
Nationaal Trial Register

Verkorte titel
BEYOND

Aandoening

Obesity

Ondersteuning

Primaire sponsor: Erasmus MC, University Medical Center Rotterdam
Overige ondersteuning: Erasmuc MC, Obstetrics and Gynaecology

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

Erasmus MC
Sam Schoenmakers

0107043599

Wetenschappelijk

Erasmus MC
Sam Schoenmakers

0107043599

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	05-01-2020
Aantal proefpersonen:	190
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	05-12-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8217
CCMO	NL OZBS72.19167

Resultaten