A randomized controlled multicenter trial comparing bariatric surgery with a structured life style intervention program in subfertile obese women with PCOS

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON55712

Source
ToetsingOnline

Brief title
Bariatric Subfertility Trial

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Pregnancy, labour, delivery and postpartum conditions
- Sexual function and fertility disorders

Synonym
Subfertility

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,aanvraag subsidie via Wetenschapsbureau Sint Franciscus Gasthuis.

Intervention

Keyword: Bariatrics, Life style intervention, PCOS, Subfertility

Outcome measures

Primary outcome

The number of healthy children, born after at least 37 weeks of gestation

during the 3 years follow-up period.

Secondary outcome

* percentage effective weight loss.

* comorbity related to bariatric surgery.

* metabolic and endocrinological changes.

* maternal, perinatal and neonatal complications.

* comorbiditty related to morbid obesity.

* quality of life.

Study description

Background summary

Obesity is an epidemic causing metabolic comorbidity (i.e. diabetes type 2, hypertension, dyslipidemia) and mortality. Besides that, obesity leads to subfertility in women due to polycystic ovarian syndrome (PCOS). Furthermore, it increases miscarriage rates and complications during pregnancy and delivery, which as a result lead to an increase in maternal and neonatal morbidity and mortality. If these obese women seek medical care for subfertility attention

focusses on the achievement of pregnancy and the consequences of metabolic syndrome (MS) can be overlooked.

Study objective

It is hypothesed that intervention (bariatric surgery) compared with control (life style intervention program) will increase fertility measured by the healthy born baby rate after at least 37 weeks of gestation (primary end point) within 3 years following therapy.

Study design

This study will be a multicenter prospective randomized controlled trial comparing conventional lifestyle intervention with bariatric surgery for subfertile obese women (BMI of 35 kg/m2 or more) with PCOS.
Intervention: bariatric surgery. Control: Life style intervention program.Power analysis (including drop outs) indicates 120 patients in both the intervention and the control group. Follow-up on an out-patient basis for 3 years.

Intervention

Bariatric surgery: Laparoscopic Roux-en-Y Gastric Bypass. Operative procedures will be performed by, or under direct supervision of a bariatric surgeon with an experience of at least 200 bariatric operations.

Study burden and risks

Risks:
Risks related to (bariatric) surgery and anaesthesia.

Extra burden for the patient:
1) Questionnaires at the intake of the study and at the follow-up visits (baseline, 6 weeks, 3, 6, 12, 24 and 36 months). The time needed to complete the questionnaires is approximately 30 minutes per visit.
2) Extra venous blood samples (ca. 50 ml) will be taken at the time of the follow-up visits.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

• Age 18-40 years
• BMI of 35 kg/m2 or more.
• Subfertile women with PCOS
• No previous fertility treatment.
• Informed consent and willing to enter the follow up program.

Exclusion criteria

• Azoospermia, severe endometriosis, WHO class III anovulation (premature ovarian
failure).
• Prior fertility treatment.
• Prior bariatric surgery.
• Prior major abdominal surgery
• ASA classification >= IV
• Severe concomitant disease.
• The inability to understand written information..

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-04-2019
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO Date:	09-06-2015
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	28-08-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	24-02-2022
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	NL47257.078.15