Bariatric Subfertility Trial

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29279

Source
Nationaal Trial Register

Health condition

Subfertility
PCOS
Morbid obesity
Bariatric surgery
Life style modification

Sponsors and support

Primary sponsor: J.S.E. Laven, MD, PhD
Erasmus Medical Center
Department of Department of Reproductive Endocrinology
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Intervention

Outcome measures

Primary outcome

The primary endpoint is the rate of healthy born baby rate after at least 37 weeks of gestation (primary end point) within three years after therapy.

Secondary outcome

Perinatal outcome and complications, percentage of women needing fertility treatment, clinical and ongoing pregnancy rates, loss of excess body weight (%EWL), improvement in obesity induced co-morbidity (MS), biochemical and hormonal changes, quality of life and medical and non-medical costs, obesity related co-morbidity as well as psychosocial performance will improve more after intervention.

Operating time, duration of hospital stay, direct health care costs, peri-operative and post-operative in-hospital mortality and morbidity following LRYGB. Morbidity is defined as reoperations, re-interventions/ reoperations, re-admissions, re-do surgery and serious adverse events. Morbidity is defined as mayor (anastomotic leakage, major peroperative blood loss due to splenic or vascular hemorrhage, pulmonary embolism, intra-abdominal abscess and intra-abdominal hematoma) or minor (wound infection, urinary tract infection and anastomotic stenosis). Moreover, the rate of extra outpatient and ER visits because of complaints following LRYGB are evaluated.

To evaluate the need for re-do surgery (need to perform an additional bariatric procedure after the performed surgery) as a result of insufficient weight loss or medical complaints within 5 years following the primary bariatric procedure (LSG or LRYGB).

To evaluate the biochemical and hormonal changes following Laparoscopic Roux-en-Y Gastric Bypass or Laparoscopic sleeve gastrectomy.

Validated Questionnaires to evaluate quality of life (QoL) following LRYGB: 1) EuroQol-5D (EQ-5D) 2) Short-form 36 (SF-36) and 3) Obesity related Quality of life the Moorehead-Ardelt II questionnaires / Bariatric Analysis and Reporting Outcome System (BAROS).

Study description

Background summary

RESEARCH QUESTION: To assess the effectiveness of bariatric surgery versus life style modification in morbidly obese subfertile women with PCOS.

HYPOTHESIS: Bariatric surgery is superior to life style modification in achieving pregnancy.

STUDY DESIGN: Randomized controlled multicenter clinical trial.

STUDY POPULATION: Subfertile PCOS patients with a BMI > 35 kg/m2.

INTERVENTION: Bariatric surgery.

USUAL CARE/COMPARISON: Life style modification.

OUTCOME MEASURES: Primary outcome measure: life born, at term, children within the 3 years follow-up period. Secondary outcome measures: effective weight loss; comorbidity related to bariatric surgery; metabolic and endocrinologic changes; maternal, perinatal and neonatal complications; comorbidity related to morbid obesity; quality of life.

SAMPLE SIZE / DATA ANALYSIS: 120 patients in both arms, based on a difference of 20% in effectiveness between both treatment options. Data analysis according to the intention to treat principle.

Study objective

The null hypothesis implies 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

Conventional fertility treatment in the investigational group will start 12 months after surgery.

Conventional fertility treatment in the control group will start 12 months after the commencement of the twelve-month lifestyle program and / or after achieving the target weight reduction of at least 5%

Follow-up will be performed in an out-patient clinical setting at 6 weeks, 3 months, 6 and 12 months and then every year for 3 years

Intervention

Bariatric surgery, Laparoscopic gastric bypass

Contacts

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Eligibility criteria

Inclusion criteria

• Age 18-40 years

• BMI > 35 kg/m2.

• Subfertile women with PCOS according to the Rotterdam criteria.

• No previous fertility treatment.

• Psychological screening.

• Informed consent and willingness to participate in the follow up program.

Exclusion criteria

• Azoospermia, endometriosis AFS class > III, WHO class III anovulation (premature ovarian failure) or endocrinopathies (such as Cushing syndrome, adrenal hyperplasia and diabetes type I).

• Pregnancy induced hypertension, preeclampsia, eclampsia or HELPP syndrome in a

previous pregnancy.

• Prior fertility treatment.

• Prior bariatric surgery.

• Prior major abdominal surgery (like colonic resection, septic abdomen, aorta surgery, which might jeopardise the possibility of execution a LSG or LRYGB)

• ASA (American Society for Anesthesiologists) classification ≥ IV

• Alcohol or drug abuse

• Severe concomitant disease (carcinomas, neurodegenerative disorders or other disorders presently representing being considered exclusion criteria for bariatric surgery)

• The inability to understand written information, necessary to give informed consent and to complete questionnaires.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2019
Enrollment:	240
Type:	Anticipated

Ethics review

Positive opinion

Date:	24-07-2018
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	NL7196
NTR-old	NTR7395
Other	METC Erasmus MC : MEC-2015-123 / NL 47257.078.15

Study results