Efficacy of Laparoscopic Roux-en-Y Gastric Bypass Surgery versus Conventional Therapy for Type 2 Diabetes Mellitus in Moderate Obese Patients with BMI of 30 -35 kg/m2: a randomized controlled trial.

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We hypothesize that laparoscopic RYGB surgery is more effective on glycaemic control than conventional therapy in moderate obese patients with BMI 30 * 35 kg/m2 .

Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON40441

Source
ToetsingOnline

Brief title
ROMEO-trial

Condition

- Other condition
- Glucose metabolism disorders (incl diabetes mellitus)
- Gastrointestinal therapeutic procedures

Synonym
Obesity, overweight

Health condition

Obesitas

Research involving
Human

Sponsors and support

Primary sponsor: Rijnstate Ziekenhuis
Source(s) of monetary or material Support: Geen externe financiering

Intervention

Keyword: Diabetes Mellitus, Obesity, Roux-en-Y Gastric Bypass

Outcome measures

Primary outcome

Complete remission of DM2 defined as FPG < 5.6 mmol/L and HbA1c < 6.0% (<42 mmol/mol) without anti-diabetic medication for minimal 1 year

Secondary outcome

Improvement of HbA1c: HbA1c difference of 1% (or 11 mmol/mol; SD 1.5% or 16.5 mmol/mol), and Achievement of HbA1c target of < 7% (< 53 mmol/mol). Body weight loss: defined as (loss of) absolute body weight, Total Body Weight Loss (%TBWL), Excess BMI loss (%EBL), excess weight loss (%EWL); Quality of life; SF-36 questionnaire, BAROS (Bariatric Analysis and Reporting Outcome System) score; Cardiovascular risk factors and 10-year cardiovascular risk estimates according to the United Kingdom Prospective Diabetes study risk engine; Microalbuminuria (urinary albumin/creatinin ratio > 2.5 g/mol for men and > 3.5 g/mol for women); surgical complication rate: such as anastomotic leakage, bleeding, wound infection, trombo-embolic events, internal hernia; vitamin

deficiencies: vitamin D, vitamin B12, folate.

Study description

Background summary

The prevalence of Type 2 Diabetes Mellitus (DM2) in the Netherlands is 600.000-800.000 and each year ~70.000 new patients are diagnosed. This increasing number of patients with DM2 is closely correlated with the obesity epidemic. In obese patients with DM2 adequate glucoregulation is often difficult to achieve because of the underlying insulin resistance. Weight loss is perhaps the most important therapeutical intervention in obese patients with DM2. Weight loss intervenes in the underlying pathophysiology and restores insulin sensitivity and sometimes even insulin secretion. Weight reducing surgery, i.e. bariatric surgery, is the only intervention that leads to persistent weight loss and it is superior above conventional (non-surgical) treatment. Meta-analyses also showed spectacular metabolic improvement of bariatric surgery in obese patients with DM2. In addition, two randomized controlled trials proved the superiority of RYGB above conventional medical treatment for treatment of DM2 in morbidly obese patients (BMI > 35 kg/m2). Remission of DM2 occurred in 75% after RYGB surgery compared to none in conventional group. Different international committees consider to expand the indications for bariatric surgery in obese patients with DM2 who don*t meet the international guidelines for bariatric surgery. The committees underline the necessary for more researches in moderate obese patients (BMI 30 - 35 kg/m2) and uncontrolled DM2 with conventional medical therapy. We therefore propose to study the effectiveness of a RYGB in moderate obese patients (BMI 30 * 35 kg/m2) with DM2.

Study objective

We hypothesize that laparoscopic RYGB surgery is more effective on glycaemic control than conventional therapy in moderate obese patients with BMI 30 * 35 kg/m2 .

Study design

A single center, non-blinded, randomized controlled trial.

Intervention

The patients will be randomized in the intervention group (RYGB) or the control group (conventional therapy group).

Study burden and risks

The study will be part of the regular medical care after Gastric Bypass or conventional diabetes therapy. There will be no extra (invasive) research moments for participatin patients; only questionnairies.

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

1. Informed consent
2. Age 18 * 50 years
3. BMI 30-35 kg/m2
4. Medical history of DM2

a. Metformin + (SU-derivate/DPP4-remmer)
b. Insulin dependent; with or without oral diabetic medication
c. GLP-1 analogue; with or without oral diabetic medication
5. HbA1c > 7.0% and Fasting Plasma Glucose (FPG) > 7.9 mmol/L

Exclusion criteria

1. No diabetes
2. History of bariatric surgery
3. C-peptide <0,27nmol/L
4. Enable to follow medical advises: language barrier, genetic disorders
5. Obesity due to medical disorder (e.g. Cushing syndrome)
6. Contra-indication for RYGB surgery: inflammatory bowel disease (Morbus Crohn / Colitis Ulcera)
7. Renal failure (MDRD < 30)
8. Pregnancy
9. Psychiatric disorder

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:	Will not start
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO Date:	30-01-2014
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL47022.091.13