Efficacy in DIabetes treatment: Surgery Or coNventional: the EDISON-trial.

No registrations found.

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

Summary

ID

NL-OMON20371

Source
NTR

Brief title
EDISON

Health condition

Diabetes Mellitus type 2 (DM type II), Obesity, suikerziekte, overgewicht, obesitas.

Sponsors and support

Primary sponsor: Leiden University Medical Center (LUMC)
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

1. HbA1c difference of 1% (or 11 mmol/mol; SD 1.5% or 16.5 mmol/mol);

2. Achievement of HbA1c target of < 7% (< 53 mmol/mol);

3. Remission of DM2 defined as FPG < 7.0 mmol/L and HbA1c < 6.5% (<48 mmol/mol).

Secondary outcome

1. Quality of life (EQ5D);

2. Body weight;

3. Cardiovascular risk factors (total cholesterol, HDL-cholesterol, triglycerides, LDL-cholesterol, systolic and diastolic blood pressure, waist circumference, 10-year cardiovascular risk estimates according to the United Kingdom Prospective Diabetes study (UKPDS) risk engine;

4. Use of medication for diabetes, dyslipidemia and blood pressure;

5. Microalbuminuria (urinary albumin/creatinin ratio > 2.5 g/mol for men and > 3.5 g/mol for women).

Study description

Background summary

The prevalence of type 2 diabetes (DM2) in the Netherlands has increased dramatically in recent years and is expected to rise to 1.3 million persons in 2025. Most DM2 patients are overweight and 30-50% have obesity (body mass index > 30 kg/m2). Current therapies for diabetes increase bodyweight even further, making it very difficult to achieve the target Hba1c level of 7% or less. Patients with DM2 have a higher risk for cardiovascular disease. The complications of DM2 seriously decrease the quality of life and the life expectancy of DM2 patients, but also have large socioeconomic consequences. Weight loss is the hallmark of therapy but unfortunately current diet, exercise or drug interventions give only modest weight reduction that is not lasting.

The only intervention with proven long-term efficacy with respect to weight loss is bariatric surgery. Furthermore, bariatric surgery appears to improve DM2 in obese DM2 patients. Therefore, the number of bariatric surgeries in obese DM2 patients is increasing. However, the scientific evidence for this operation procedure is scarce and largely emanates from a meta-analysis mostly containing retrospective analyses of databases. Furthermore, the cost-effectiveness of RYGB versus conventional treatment of DM2 patients with a BMI > 35 kg/m2 has not been established. From both the patient as well as a socioeconomic perspective this procedure might be of great importance.

In this trial we investigate if RYGB is more (cost-)effective in the long-term than conventional therapy in DM2 patients with a BMI > 35 kg/m2 not adequately regulated by dual oral therapy.

Study objective

The prevalence of type 2 diabetes (DM2) in the Netherlands has increased dramatically in recent years and is expected to rise to 1.3 million persons in 2025. Most DM2 patients are overweight and 30-50% have obesity (body mass index > 30 kg/m2). Current therapies for glucoregulation, with the exception of metformin and glucagon-like peptide-1 (GLP-1) analogues, increase bodyweight even further. The ensuing aggravation of insulin resistance makes it very difficult to achieve the target Hba1c level of 7% or less. Above this value the risk of chronic micro-and macrovascular complications rise dramatically. In fact, patients with DM2 have a 2-4 times increased risk for cardiovascular disease.These complications seriously decrease the quality of life and the life expectancy of DM2 patients, but also has large socioeconomic consequences. In 2005 health care costs associated with DM2 in the Netherlands amounted 814 million euro and indirect costs are unknown. Weight loss is the hallmark of therapy but unfortunately current diet, exercise or drug interventions give only modest weight reduction that is not lasting.
The only intervention with proven long-term efficacy with respect to substantial (10 kilograms or more) weight loss is bariatric surgery. Furthermore, bariatric surgery appears to improve DM2 in obese DM2 patients. Therefore, the number of bariatric surgeries in obese DM2 patients is increasing. However, there is currently only 1 prospective randomized controlled trial specifically addressing the efficacy of gastric banding versus conventional therapy in obese DM2 patients. This study showed a large benefit of gastric banding as compared to conventional therapy and was cost-effective at the short and long-term. Current practise in the Netherlands is to do a laparoscopic Roux-en-Y Gastric bypass (RYGB) procedure in obese patients with DM2, not gastric banding. The scientific evidence for this operation procedure is scarce and largely emanates from a meta-analysis mostly containing retrospective analyses of databases. In this meta-analysis the bypass was nevertheless more effective in both reducing bodyweight (-41% vs. 65.7% of the excess weight) and HbA1c (47.9% vs. 83.7% improvement of glucoregulation). Furthermore, the cost-effectiveness of RYGB versus conventional treatment of DM2 patients with a BMI > 35 kg/m2 has not been established. From both the patient as well as a socioeconomic perspective this procedure might be of great importance.

Hypothesis:

We hypothesize that RYGB is more cost-effective in the long-term than conventional therapy in DM2 patients with a BMI > 35 kg/m2 not adequately regulated by dual oral therapy who according to the Dutch Guidelines of General practitioners (standaarden van Nederlands Huisarts Genootschap) should commence insulin therapy.

Study design

0, 3, 6, 12, 24 and 36 months.

Intervention

1. Roux-en-Y Gastric bypass (RYGB);

2. Conventional treatment arm: standard of care according to the Dutch Guidelines of General practitioners (NHG standard).

Contacts

Public
Postbus 9600
M.A. Sleddering
Leids Universitair Medisch Centrum
Afdeling Algemene Interne Geneeskunde, C4-R
Leiden 2300 RC
The Netherlands
+31 (0)71 5264327
Scientific
Postbus 9600
M.A. Sleddering
Leids Universitair Medisch Centrum
Afdeling Algemene Interne Geneeskunde, C4-R
Leiden 2300 RC
The Netherlands
+31 (0)71 5264327

Eligibility criteria

Inclusion criteria

1. Informed consent;

2. Age 18-60 years (current criteria, age can be expanded if patient is in good condition but with a limit to 70 years);

3. DM2;

4. Fasting plasma c-peptide > 0.8 ng/ml;

5. HbA1c > 7.0% despite diet/lifestyle advises and 2 glucose-lowering drugs with the exception of insulin;

6. BMI> 35 kg/m2 and <45 kg/m2;

7. Has attempted to lose weight without (lasting) success.

Exclusion criteria

1. Use of insulin;

2. Substance abuse/dependence;

3. Mentally instable/psychiatric disorder (according to evaluation psychologist);

4. Some eating disorders;

5. Physical condition not good enough to sustain operation: IFSO and ASA criteria;

6. No diabetes type 2;

7. Fasting plasma c-peptide < 0.8 ng/ml;

8. Pregnancy.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-01-2011
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion

Date:	20-01-2011
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	NL2577
NTR-old	NTR2703
Other	METC LUMC : P10-202
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A