# Efficacy and costs of Roux-en-Y gastric bypass surgery versus conventional treatment of type 2 diabetes patients with a BMI > 35 kg/m2: a prospective randomized controlled trial

Published: 06-12-2010
Last updated: 28-09-2024

To evaluate the effect and costs of a RYGB vs conventional therapy as glucoregulatory treatment for DM2 patients with a BMI>35 kg/m2 and HbA1c >7% despite 2 blood glucose lowering agents (not being insulin).

| | |
|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Glucose metabolism disorders (incl diabetes mellitus) |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON34324

**Source**
ToetsingOnline

**Brief title**
RCT in DM2 patients with BMI >35 kg/m2: RYGB vs conventional therapy

### Condition

- Glucose metabolism disorders (incl diabetes mellitus)

**Synonym**
diabetes type 2, sugar disease

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Leids Universitair Medisch Centrum
**Source(s) of monetary or material Support:** ZonMw doelmatigheidsonderzoek

## Intervention

**Keyword:** conventional therapie, obesity, RYGB, type 2 diabetes

## Outcome measures

### Primary outcome

Difference between the intervention groups in HbA1c, percentage with Hba1c <7%,

percentage with diabetes remission (FPG <7.1 mmol/L, HbA1c <6.5% without

medication)

cost-utility analysis from a social perspective

### Secondary outcome

quality of life, body weight, cardiovascular risk factors and 10-year

cardiovascular risk.

# Study description

### Background summary

600.000-800.000 people have type 2 diabetes (DM2) in the Netherlands, with 70.000 new patients yearly. Most DM2 patients are obese. DM2 is a chronic progressive disease. Presently,no pharmacological intervention integrally treats the underlying pathophysiological process. Weight loss is the most important therapeutical measure, but the effect of diet, exercise and drugs is marginal and short-lived. Bariatric surgery, especially Roux-en-Y gastric bypass (RYGB), effectively reduces glucose levels and bodyweight in obese DM2 patients. Dutch treatment guidelines do not include specific recommendations for obese DM2 patients. Most patients are treated with multiple (expensive) drugs while the HbA1c target of <7% is often not achieved and the disease progresses. A RYGB might be a more effective alternative. Initial costs will be

higher than pharmacotherapy, but in the long term savings are expected due to greater effectiveness. Class I evidence endorsing the (cost-)effectiveness of a RYGB versus conventional treatment for obese DM2 patients is lacking.

### Study objective

To evaluate the effect and costs of a RYGB vs conventional therapy as glucoregulatory treatment for DM2 patients with a BMI>35 kg/m2 and HbA1c >7% despite 2 blood glucose lowering agents (not being insulin).

### Study design

prospective, randomized, controlled, multicenter trial.

### Intervention

RYGB surgery versus conventional therapy for DM2 (NHG standaard) and obesity (CBO guideline)

### Study burden and risks

We compare the costs and effectiveness of 2 registred interventions for the treatment of obese DM 2 patients. The treating physician is the one primarily responsible for the treatment of his/her patient.
The study only measures the outcomes of these 2 interventions. For the study patients have to visit the research phycisian 8 times over a period of 3 years. Given the importance of the oucome of this investigation this burden is minimal en defiable.

## 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

• Informed consent
• Age 18-60 years
• DM2
. fasting c-peptide > 0.8 ng/ml
• HbA1c > 7.0 % despite diet/lifestyle advises and 2 glucose-lowering drugs with the exception of insulin
• BMI> 35 kg/m2 and <45 kg/m2
• Has attempted to lose weight without (lasting) succes

## Exclusion criteria

• Use of insulin
• Substance abuse/dependence
• Mentally instable/psychiatric disorder (according to evaluation psychologist)
• Some eating disorders
. no diabetes type 2, fasting c-peptide < 0.8 ng/ml
• Physical condition not good enough to sustain operation: IFSO and ASA criteria

# Study design

## Design

Study type: Interventional

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

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-03-2011 |
| Enrollment: | 100 |
| Type: | Actual |

## Ethics review

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|---|---|
| Approved WMO Date: | 06-12-2010 |
| Application type: | First submission |
| Review commission: | METC Leids Universitair Medisch Centrum (Leiden) |
| Approved WMO Date: | 16-02-2012 |
| Application type: | Amendment |
| Review commission: | METC Leids Universitair Medisch Centrum (Leiden) |

## 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 | NL33979.058.10 |