Faecal reference values after Roux-en-Y gastric bypass

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Because of modified anatomy of the gastro-intestinal tract after RYGB, which affects digestion and absorption of food, it is hypothesized that faecal composition after RYGB is also changed.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON28438

Bron
Nationaal Trial Register

Aandoening

Roux-en-Y Gastric Bypass, morbid obesity, faecal, calprotectin, elastase, alpha-1-antitrypsin.

Ondersteuning

Primaire sponsor: Slotervaart Hospital

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Determination of reference values of faecal calprotectin, elastase-1 and alpha-1-antitrypsin after RYGB

Toelichting onderzoek

Achtergrond van het onderzoek

The aim of this study is to determine reference values of faecal calprotectin, elastase-1 and alpha-1-antitrypsin after Roux-en-Y Gastric Bypass procedure (RYGB).

The prevalence of morbid obesity, and its associated comorbidities, is increasing worldwide. Bariatric surgery is the most effective long-term solution of morbid obesity, RYGB being one of the most performed procedures with a presumed restrictive and malabsorptive effect.

RYGB changes the anatomy of the gastro-intestinal tract. It affects the digestion and absorption of food in the bowel, which makes it likely to also affect the composition of faeces. In clinical practise, faecal measurements are used to diagnose, rule out or monitor the course of diseases.

Calprotectin is widely used as a diagnostic and prognostic marker of inflammatory bowel diseases. Faecal elastase-1 can be determined to diagnose and monitor patients with exocrine pancreatic insufficiency. Faecal alpha-1-antitrypsin is used to diagnose a protein-losing enteropathy.

A recent study showed significant changes in the faecal calprotectin and elastase-1 concentration in 7 patients after RYGB, compared to obese controls. To determine faecal reference values after RYGB keeps non-invasive faecal diagnostic tests in use for these patients and may contribute to better understanding of gut function and adaptation after RYGB.

Doel van het onderzoek

Because of modified anatomy of the gastro-intestinal tract after RYGB, which affects digestion and absorption of food, it is hypothesized that faecal composition after RYGB is also changed.

Onderzoeksopzet

Between 12 and 24 months post-operative.

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

-Patients who are 12-24 months post-RYGB.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Patients who have diarrhoea at the time of faeces collection

- Patients who use a PPI or NSAID, without the possibility to discontinue this medication for at least 3 days

- Patients with an acute or chronic disease of stomach, intestine or pancreas which may influence the measurements made in this study.

E.g.: inflammatory bowel disease, malignancy of stomach, intestine or pancreas, chronic pancreatitis, chronic bowel infection, resection of stomach or bowel other than RYGB,

radiotherapy with the gut laying within the ablated area, systemic disease which influences the gastro-intestinal tract (e.g. systemic sclerosis)

Not excluded are patients with e.g. cholecystectomy, bacterial gastro-enteritis or acute pancreatitis, provided that patients are fully recovered.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-09-2014
Aantal proefpersonen:	120
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	27-08-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4610
NTR-old	NTR4761
Ander register	METC Slotervaartziekenhuis : P1437

Resultaten

Samenvatting resultaten
N/A