Intestinale inflammatie in patienten met een ileostoma of transversostoma - een pilot studie

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Objective: The aim of this pilot study is to investigate the degree and stability of intestinal inflammation in patients with a stoma on the ileum. Secondly, we want to validate a technique using filter papers to quantify intestinal inflammation in...

Ethische beoordeling	Goedgekeurd WMO
Status	Zal niet starten
Type aandoening	Maagdarmstelselontstekingsaandoeningen
Onderzoekstype	Observationeel onderzoek, met invasieve metingen

Samenvatting

ID

NL-OMON35630

Bron
ToetsingOnline

Verkorte titel
Intestinale inflammatie - een pilot studie

Aandoening

- Maagdarmstelselontstekingsaandoeningen

Synoniemen aandoening
inactiviteitsenteritis, uitsluitingsenteritis

Betreft onderzoek met
Mensen

Ondersteuning

Primaire sponsor: Universiteit Maastricht
Overige ondersteuning: Ministerie van OC&W

Onderzoeksproduct en/of interventie

Trefwoord: intestinale inflammatie, uitsluitingsenteritis

Uitkomstmaten

Primaire uitkomstmaten

Main study parameters/endpoints: the main endpoint of the study is intestinal inflammation as measured by markers in mucosal exudate. Markers that will be measured with the filter paper technique as described by Carty et al, are calprotectin, lactoferrin, pentraxin-3, IL-6, IL-8, IL-10, MPO and TNF-alpha.

These values will be correlated with histologic findings in biopsies.

Additional Paneth cell function will be analysed as well as mRNA and protein expression of FXR, ileal bile acid binding protein and apical sodium-dependent bile-salt transporter.

Secundaire uitkomstmaten

nvt

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: To investigate the effect of nutritional interventions upon intestinal inflammation, a human model with low grade intestinal inflammation is necessary. In the past, patients with ulcerative colitis in remission have been subject of study, but the disadvantage of this model is that there may be genetic differences which cause inflammation in these patients which can confound the results. Patients with a stoma on their transverse colon to protect the anastomosis after partial colonic resection suffer from diversion colitis, which is intestinal inflammation that attenuates after bowel continuity is restored. Since these patients have a normal colon mucosa before the stoma is constructed, are generally in a good condition and and do not suffer from clinical relevant symptoms, this model can be ultimately suitable to investigate the effect of nutritional interventions. Similar to the

development of abnormalities in the large intestine in patients with a transverse stoma, abnormalities are also observed in the bypassed part of the small intestine in patients with an ileostomy. Most likely, lack of bile in the bypassed small intestine is responsible for these abnormalities. Recently, bile acids have shown to be natural ligands for the farnesoid X receptor (FXR), a ligand-activated nuclear receptor transcription factor predominantly residing the epithelium of the ileum. In animal studies it has been shown that FXR-agonists protect against intestinal bacterial overgrowth and maintain intestinal integrity. To the best of our knowledge, human studies exploring the role of the FXR are lacking. When the FXR has proven to be involved in bile acid binding, it may be appealing to supply specific FXR agonists that are currently available in order to restore gut health.

Doel van het onderzoek

Objective: The aim of this pilot study is to investigate the degree and stability of intestinal inflammation in patients with a stoma on the ileum. Secondly, we want to validate a technique using filter papers to quantify intestinal inflammation in these patients.

Onderzoeksopzet

Study design: an observational design.

Inschatting van belasting en risico

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
The patients included in this pilot study are not minors or incapacitated persons.
After informed consent is obtained, the patients will be asked to fill out a general questionnaire about medical history and diet preferences. This will take approximately 20 minutes.
The expected burden for the patient related to the endoscopic procedure is as follows: the first planned endoscopy is part of regular care, during this procedure patency of the anastomosis is checked. The second endoscopy is not regular care, but will be done just before the stoma will be closed in the operating room. The patient will be under general anesthesia, just before the operation is started a second endoscopy will be performed. In this way the discomfort for the patient is minimized. An endoscopy takes about 20 minutes. During endoscopy we will use filter papers to absorb mucosal exudates; no risks are associated with this method. Three biopsies will be taken during endoscopy in the afferent loop as well as in the efferent loop of the stoma (in total 6 biopsies). The risk of taking biopsies during endoscopy is bowel perforation. The risk of bowel perforation and bleeding is very low, (0.08%) at the biopsy sites 2. However, this risk is expected to be much smaller in the present

study, because no severely ill subjects will be recruited. Complications mainly appear after removal of polyps. A report of the *gezondheidsraad* mentions a risk of 0.0025% risk of perforation after screening for cancer in healthy subjects, which will be similar in patients with an ileostomy.

Contactpersonen

Publiek

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Wetenschappelijk

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Nederland

Locaties

Landen waar het onderzoek wordt uitgevoerd

Netherlands

Deelname eisen

Leeftijd
Volwassenen (18-64 jaar)
65 jaar en ouder

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- ileo- of transversostoma

- tenminste 1 maand geleden geconstrueerd stoma
- boven 18 jaar
- schriftelijk informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- inflammatoire darmziekte (zoals Crohn, Colitis Ulcerosa
- stoma op dunne darm boven het ileum
- antibiotische behandeling minder dan een maand geleden

Onderzoeksopzet

Opzet

Type: Observationeel onderzoek, met invasieve metingen

Blindering:	Open / niet geblindeerd
Controle:	Geen controle groep
Doel:	Behandeling / therapie

Deelname

Nederland

Status:	Zal niet starten
Aantal proefpersonen:	10
Type:	Verwachte startdatum

Ethische beoordeling

Goedgekeurd WMO

Datum:	06-08-2008
Soort:	Eerste indiening
Toetsingscommissie:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Goedgekeurd WMO

Datum:	12-04-2010
Soort:	Amendement

Toetsingscommissie:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
CCMO	NL23566.068.08