Endoscopic Balloon Dilatation of narrowed intestinal connection in Crohn's disease with or without extra local medication

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It is beneficial to add intensive local anti-inflammatory therapy (Triamcinolone injection therapy combined with 9 mg oral BudenoFalk once daily for 24 weeks) to routine enteric balloon dilatation in Crohn's disease patients with symptomatic...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24606

Bron
Nationaal Trial Register

Verkorte titel
ENDO-ACE

Aandoening

Morbus Crohn
Status after ileocecal resection
Stenosis anastomosis

Ondersteuning

Primaire sponsor: Drs. C.G. Noomen
Department of Gastroenterology
Leiden Universitary Medical Center
Albinusdreef 2
Postbus 9600
2300 RC Leiden

The Netherlands
Tel.: ++31-71-5261838
Fax: ++31-71-5266979
E-mail: c.g.noomen@lumc.nl
Overige ondersteuning: Initiator

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To evaluate the benefit of the addition of intensive local anti-inflammatory therapy to routine enteric balloon dilatation in Crohn´s disease patients with symptomatic stenosis of the anastomosis.

Toelichting onderzoek

Achtergrond van het onderzoek

The primary objective of this study is to evaluate the benefit of adding intensive local anti-inflammatory therapy (Triamcinolone injection therapy combined with 9 mg oral BudenoFalk once daily for 24 weeks) to routine enteric balloon dilatation in Crohn´s disease patients with symptomatic anastomosis

Doel van het onderzoek

It is beneficial to add intensive local anti-inflammatory therapy (Triamcinolone injection therapy combined with 9 mg oral BudenoFalk once daily for 24 weeks) to routine enteric balloon dilatation in Crohn's disease patients with symptomatic anastomosis.

Onderzoeksopzet

- Triamcinolone injection therapy combined with 9 mg oral BudenoFalk once daily for 24 weeks

- 1/10/2008 - 1/10/2010

Onderzoeksproduct en/of interventie

- Triamcinolone injection therapy combined with 9 mg oral BudenoFalk once daily for 24 weeks

- IBDQ, Harvey-Bradshaw score and VAS scores will be obtained at defined points.

- MR enterography will be performed.

- Colonoscopy with fluoroscopy under conscious sedation.

- Asessment of Rutgeerts score during colonoscopy.

- An EBD will be performed during the same colonoscopy session.

- At defined points blood samples will be taken

Contactpersonen

Publiek

Leiden Universitary Medical Center (LUMC)
Department of Gastroenterology
Postbus 9600

C.G. Noomen
Albinusdreef 2

Leiden 2300 RC
The Netherlands
+31 (0)71 5261838

Wetenschappelijk

Leiden Universitary Medical Center (LUMC)
Department of Gastroenterology
Postbus 9600

C.G. Noomen
Albinusdreef 2

Leiden 2300 RC
The Netherlands
+31 (0)71 5261838

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Informed consent

2. Man or woman between 18 and 75 years of age

3. Established diagnosis of Crohn's disease

4. Negative stool culture (for exclusion of infectious ileocolitis and Clostridium Difficile infection)

5. History of ileocecal resection

6. Symptoms of intestinal obstruction;

- Intermittent abdominal pain

- Abdominal distension

- Nausea

- Vomiting

- Anorexia

- Significant stenotic segment (defined as a decrease in calibre of the intestinal lumen causing a pre-stenotic dilatation) located at the anastomosis as diagnosed with MR enterography.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. A stenotic segment of more than 6 cm

2. Rutgeerts score i4 inflammation at the site of stenosis

3. Fistulas at the site of stenosis or in the near proximity

4. A stenosis that cannot be properly endoscopically visualized

5. A significant stenosis proximal to the stenotic anastomosis
6. The concomitant use of other oral drugs containing budesonide within 4 weeks of screening

7. Oral antibiotics within 4 weeks of screening.

8. Pregnancy, lactation, or intended pregnancy or intended impregnation within 9 months

9. Serious secondary illnesses of an acute or chronic nature (e.g., acute cardiovascular disease, active infection)

10. Active infection

11. Known intolerance/hypersensitivity to the study drug

12. Well-founded doubt about the patient's cooperation and/or compliance

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-10-2008
Aantal proefpersonen:	36
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL1321
NTR-old	NTR1378
Ander register	:
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A