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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24606

Source
Nationaal Trial Register

Brief title
ENDO-ACE

Health condition

Morbus Crohn
Status after ileocecal resection
Stenosis anastomosis

Sponsors and support

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Source(s) of monetary or material Support: Initiator

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

- To assess the feasibility of radiologic imaging of the anastomosis in the endoscopy suite, and validating Radiological Crohn´s Disease Anastomotic Index (RCDAI).

- To assess the safety of EBD procedure in combination with local intensive therapy

Study description

Background summary

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

Study objective

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.

Study design

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

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

Intervention

- 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

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2008
Enrollment:	36
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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	NL1321
NTR-old	NTR1378
Other	:
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A