Comparison between tacrolimus suppositories and beclomethasone suppositories for rectal inflammation, not responding to previous 5-ASA treatment.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21626

Source
Nationaal Trial Register

Brief title
TSP study

Health condition

Ulcerative proctitis

Sponsors and support

Primary sponsor: Erasmus MC
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

Proportion of patients in clinical remission and endoscopic remission after 28 days of

treatment.
Clinical remission is defined as a decrease in CAI score ¡Ü 1 with rectal bleeding and stool frequency scores of 0. Endoscopic remission is defined as no mucosal friability, and a ¡Ý 1-point reduction in sigmoidoscopy score from baseline.

Secondary outcome

-Proportion of patients responding (the proportion of patients achieving clinical improvement, defined as a decrease of ¡Ý3 points from baseline in the total CAI score) and the changes in sigmoidoscopic mucosal appearance (baseline to week 4)
-Safety and tolerability of tacrolimus suppositories and beclomethasone suppositories.
-Quality of life (IBDQ).
-Changes in histopathology from biopsies taken before and after treatment (grading scale (0_ structural changes only, 1_ chronic inflammation, 2 _ lamina propria neutrophils, 3_neutrophils in epithelium, 4 _ crypt destruction, 5 _ erosions or ulcers)).

Study description

Background summary

Randomized, double blind, controlled, multi-center study in Dutch university hospitals. The total follow-up period is 4 weeks.

Study objective

A subset of patients with ulcerative colitis have disease limited to only the rectum. Most patients will reach remission with conventional 5-ASA or corticosteroid treatments. However, there have been few studies investigating treatment options in patients who are resistant to this conventional therapy.
Previous pilot studies have shown that approximately 80% of patients with refractory proctitis respond well to topical tacrolimus treatment.
The aim of this study is to assess the efficacy of tacrolimus suppositores compared to beclomethasone suppositories, in a randomized controlled, double-blind fashion.

Study design

Total follow-up period per patient: 4 weeks

Intervention

Arm A: tacrolimus suppositories
2mg, once daily, for 28 days
Arm B: beclomethasone suppositories

3mg, once daily, for 28 days

Contacts

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Eligibility criteria

Inclusion criteria

Refractory ulcerative proctitis at least 3 months before randomization, proven endoscopically (inflammation grade score 2 or higher) or histologically (grading scale
2 or higher).
Proctitis is defined as disease activity up to 20 cm beyond the anal verge.
Refractory proctitis defined as a failure to at least the use of 5-asa suppositories of a maximum of 1 gram for at least 21 days and recurrent proctitis is defined as relapse within 3 months after stopping of local adequate 5-asa treatment.
Endoscopy may have been performed up to 3 weeks before screening, if the endoscopy was well documented and biopsies were taken.
Age 18-70 years.
Written informed consent.
Permitted concomitant therapy: aminosalicylates, azathioprine, 6-mercatopurine and methotrexate at stable dose for 12 weeks,

Exclusion criteria

Use of enemas within 14 days prior to randomization
Infliximab or other anti TNF treatment within 12 weeks prior to randomization
Treatment with tacrolimus prior to randomization

Treatment with any investigational drug within 12 weeks of randomization
Treatment with any form of corticosteroids within 4 weeks of randomization
Abnormal renal function (eGFR < 30 mL/min)
Presence of ova, parasites, toxins or other signs of infectious agents in stool sample.
Pre-existent leucopenia or thrombopenia (neutrophil count < 1,800/mm3 or platelets < 90,000/mm3)
Liver function tests abnormalities (>2 ULN).
Other significant medical illness that might interfere with this study:
Current malignancy, immunodeficiency syndromes.
Any known pre-existing medical condition that could interfere with the patient's participation in and completion of the study such as:
- Pre-existing psychiatric condition, especially depression, or a history of severe psychiatric disorder, such as major psychoses, suicidal ideation and/or suicidal attempt are excluded. Severe depression would include the following: (a) subjects who have been hospitalized for depression, (b) subjects who have received electroconvulsive therapy for depression, or (c) subjects whose depression has resulted in a prolonged absence of work and/or significant disruption of daily functions. Subjects with a history of mild depression may be considered for entry into the protocol provided that a pretreatment assessment of the subject¡¯s mental status supports that the subject is clinically stable and that there is ongoing evaluation of the patient¡¯s mental status during the study
- CNS trauma or active seizure disorders requiring medication
- Significant cardiovascular dysfunction within the past 6 months (e.g. angina, congestive heart failure, recent myocardial infarction, severe hypertension or significant arrhythmia).
- Poorly controlled diabetes mellitus
- Significant pulmonary dysfunction/chronic disease (e.g. chronic obstructive pulmonary disease)
- Renal insufficiency (elevated serum creatinine)
- Pregnancy, lactation
- Substance abuse, such as alcohol (80 gram/day), I.V. drugs and inhaled drugs. If the subject has a history of substance abuse, to be considered for inclusion into the protocol, the subject must have abstained from using the abused substance for at least 2 years. Subjects receiving methadone within the past 2 years are also excluded
- Positive stool culture for enteric pathogens
- Any other condition which in the opinion of the investigator would make the patient unsuitable for enrollment, or could interfere with the patient participating in and completing the study.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2014
Enrollment:	88
Type:	Anticipated

Ethics review

Positive opinion

Date:	30-01-2014
Application type:	First submission

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	NL4205

Register	ID
NTR-old	NTR4416
Other	ZonMW : 80-83600-98-10006

Study results

Summary results

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