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

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21626

Bron
Nationaal Trial Register

Verkorte titel
TSP study

Aandoening

Ulcerative proctitis

Ondersteuning

Primaire sponsor: Erasmus MC
Overige ondersteuning: ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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

Doel van het onderzoek

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.

Onderzoeksopzet

Total follow-up period per patient: 4 weeks

Onderzoeksproduct en/of interventie

Arm A: tacrolimus suppositories
2mg, once daily, for 28 days
Arm B: beclomethasone suppositories
3mg, once daily, for 28 days

Contactpersonen

Publiek

Erasmus MC
Postbus 2040
M. Lie
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The Netherlands

Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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,

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-02-2014
Aantal proefpersonen:	88
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	30-01-2014
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	NL4205
NTR-old	NTR4416
Ander register	ZonMW : 80-83600-98-10006

Resultaten

Samenvatting resultaten

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