# Mesenchymal stromal cell therapy for the treatment of proctitis in ulcerative colitis

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Endoscopic application of mesenchymal stromal cell therapy is safe in patients with ulcerative proctitis.

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|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving nog niet gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON21802

**Bron**
NTR

**Verkorte titel**
MSC-P

**Aandoening**

Ulcerative Colitis
Colitis Ulcerosa
Inflammatory Bowel Diseases

### Ondersteuning

**Primaire sponsor:** Leiden University Medical Center
**Overige ondersteuning:** Initiator = sponsor

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

The safety and tolerability of endoscopic injected MSCs in the distal colon of patients with

refractory proctitis after 6 weeks.

# Toelichting onderzoek

### Achtergrond van het onderzoek

Patients with inflammatory bowel disease can present with proctitis. Although most of the patients with proctitis respond to conventional local 5-aminosalicylicacid (5-ASA) or corticosteroid treatment, a subset does not. For this group the next treatment option is a systemic immunosuppressive drug with considerable side-effects. In this study the safety, tolerability and feasibility of endoscopic injected allogeneic bone marrow derived mesenchymal stromal cells (MSCs) in refractory proctitis will be assessed. Fourteen patients will receive allogeneic bone marrow derived MSCs. MSCs will be injected during endoscopy in 4 to 8 places in the inflamed rectum (number of injections depending on the length of inflammation). The primary endpoint of this study will be safety after 6 weeks.

### Doel van het onderzoek

Endoscopic application of mesenchymal stromal cell therapy is safe in patients with ulcerative proctitis.

### Onderzoeksopzet

Week 2, 6, 12 and 24.

### Onderzoeksproduct en/of interventie

Fourteen patients will receive allogeneic BMMSCs. BMMSCs will be injected during endoscopy in the inflamed rectum. Seven patients will be treated with 5x106 MSCs/ spot and seven patients with 10x106 MSCs/ spot.

# Contactpersonen

## Publiek

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### Wetenschappelijk

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

a) Men and women ≥ 18 years of age;

b) Patient must have UC confirmed by endoscopic and histologic evidence;

c) Inflammation must be limited to the rectum (up to 15 cm beyond the anal verge), confirmed by endoscopy maximum 3 months before baseline (slight inflammation in other parts of the colon is accepted with a maximum Mayo Score of 1);

d) Moderate to severe proctitis indicated by a Mayo Score of 2 or 3;

e) Proctitis must be refractory to conventional medical therapy. Which means that at some time during the course of the disease, patient must have received rectal 5-ASA therapy and rectal corticosteroid therapy for at least 4 weeks which did not result in an adequate response to treatment;

f) If treated with rectal therapy, therapy must be stopped two weeks before endoscopic implantation of MSCs and only restarted after 6 weeks;

g) If treated with oral 5-ASA therapy, dose must be stable for 4 weeks prior to study entry and remain on same dose during the first 6 weeks after MSC treatment;

h) If treated with oral corticosteroids, dose must be stable for 2 weeks prior to study entry and remain on same dose during the first 6 weeks after MSC treatment;

i) If treated with 6-mercaptopurine, methotrexate, azathioprine, vedolizumab or anti-TNF therapy patients must have been on medication for 3 months and a stable dose for 2 months prior to study entry and remain on same dose during the first 6 weeks after MSC treatment;

j) If female and of child-bearing age, patient must be non-pregnant, non-breastfeeding, and use adequate contraception;

k) Patient is willing to participate in the study and has signed the informed consent.

Consent must be obtained prior to any study procedure.

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

a) Patients suffering from renal- or hepatic failure;

b) Use of any investigational drug within 1 month prior to screening or within 5 half-lives of the investigational agent, whichever is longer;

c) Positive stool culture for enteric pathogens (salmonella, shigella, and campylobacter), positive C. difficile toxin, or positive stool ova and parasite exam;

d) All active infections requiring treatment;

e) Patients who had tuberculosis or an opportunistic infection (e.g., herpes zoster [shingles], cytomegalovirus, Pneumocystis carinii, aspergillosis, histoplasmosis) within 6 months prior to screening;

f) Malignancy within the past 5 years (except for squamous or basal cell carcinoma of the skin that has been treated with no evidence of recurrence);

g) Any dysplasia in the colon in the past 5 years;

h) Very severe proctitis; expected to result in hospitalization/ surgery within 3 months;

i) Previous treatment with allogeneic MSCs;

j) 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;

k) Patient is unwilling or unable to comply with the study procedures.

## Onderzoeksopzet

### Opzet

Type: Interventie onderzoek

| | |
|---|---|
| Onderzoeksmodel: | Anders |
| Toewijzing: | Niet-gerandomiseerd |
| Blindering: | Open / niet geblindeerd |
| Controle: | N.v.t. / onbekend |

### Deelname

Nederland

| | |
|---|---|
| Status: | Werving nog niet gestart |
| (Verwachte) startdatum: | 01-03-2017 |
| Aantal proefpersonen: | 14 |
| Type: | Verwachte startdatum |

## Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 13-11-2017 |
| Soort: | Eerste indiening |

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 48876
Bron: ToetsingOnline
Titel:

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

### In overige registers

| Register | ID |
|---|---|
| NTR-new | NL6949 |
| NTR-old | NTR7205 |
| CCMO | NL63157.000.17 |
| OMON | NL-OMON48876 |

# Resultaten