The TURN trial, Transplantation of faeces in Ulcerative colitis; Restoring Nature's homeostasis.

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We hypothesize that faecal transplantation from a healthy donor can restore the dysbiosis present in UC patients, thereby inducing remission of the chronic inflammation of the colonic mucosa.

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

Samenvatting

ID

NL-OMON23236

Bron
NTR

Verkorte titel
The TURN trial

Aandoening

ulcerative colitis, colitis ulcerosa, IBD

Ondersteuning

Primaire sponsor: Academic Medical Center (AMC)
Overige ondersteuning: Academic Medical Center (AMC), ZON-MW.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Co-primary endpoint of clinical remission, as well as reduction of Mayo endoscopic inflammation score at 12 weeks after treatment.

Toelichting onderzoek

Achtergrond van het onderzoek

Ulcerative colitis (UC) is a chronic inflammatory bowel disease (IBD) of the colon. Complaints such as abdominal pain, cramps and bloody diarrhoea usually start in early adulthood and lead to life-long substantial morbidity. There is no medical treatment available that meets the desired criteria of high efficacy versus low adverse effects. The current prevailing hypothesis regarding the cause of UC states that the pathogenesis involves an inappropriate and ongoing activation of the mucosal immune system driven by the intestinal microbiota in a genetically predisposed individual. Systematic investigation into the effect of correcting the dysbiosis in ulcerative colitis patients has never been performed. The most radical way to restore the presumably disturbed natural homeostasis in UC is to perform faecal transplantation from a healthy donor.
In this trial the potential beneficial effects of restoring microbial homeostasis by faecal transplantation through a duodenal tube will be studied in a phase II randomised placebo controlled design.

Endpoints are clinical remission and reduction of endoscopic inflammation after 12 weeks (primary), as well as time to recurrence, intra individual changes in faecal samples and mucosal biopsies. Follow up is 12 months.

Doel van het onderzoek

We hypothesize that faecal transplantation from a healthy donor can restore the dysbiosis present in UC patients, thereby inducing remission of the chronic inflammation of the colonic mucosa.

Onderzoeksopzet

Week: 0, 3, 6, 12, 16, 24, 32, 40 and 52.

Onderzoeksproduct en/of interventie

Arm 1: Patients will be treated with faecal transplantation, processed for duodenal-tube infusion;

Arm 2: Patients will be treated with their own faeces (placebo), processed for duodenal-tube infusion.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients 18 years or older;

2. Established ulcerative colitis with known involvement of the left colon;

2. Simpe Clinial Colitis Activity Index of > 4 and < 11;

3. Endoscopic Mayo score of > 1;

4. In case of use of medication: Stable dose of thiopurines, 5-ASA, or corticosteroids in preceding 8 weeks.

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

1. Condition leading to profound immunosuppression;

2. Anti-TNF treatment in preceding 2 mths;

3. Ciclosporine treatment in preceding 4 wks;

4. Use of Methotrexaat in preceding 2 mths;

5. Prednisolone dose > 10 mg;

6. Life expectancy < 12 mths;

7. Use of systemic antibiotics in preceding six weeks;

8. Use of probiotic treatment in preceding 6 weeks;

9. Positive stool cultures for common enteric pathogens (Salmonella, Shigella, Yersinia, Campylobacter, enteropathogenic e coli);

10. History of surgery: hemicolectomie (defined as: surgery resulting in a resection of > 1/2 of the colon), presence of a pouch due to surgery, presence of stoma;

11. Known intra-abdominal fistula;

12. Pregnancy or women who give brestfeeding;

13. Vasopressive medication, icu stay;

14. Signs of ileus, diminished passage;

15. Allergy to macrogol or substituents, eg peanuts, shellfish.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd

Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	21-04-2011
Aantal proefpersonen:	40
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	21-04-2011
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	NL2724
NTR-old	NTR2862
Ander register	MEC AMC : 11/005
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A