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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23236

Source
NTR

Brief title
The TURN trial

Health condition

ulcerative colitis, colitis ulcerosa, IBD

Sponsors and support

Primary sponsor: Academic Medical Center (AMC)
Source(s) of monetary or material Support: Academic Medical Center (AMC), ZON-MW.

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

1. SCCAI score reduction at t=6 weeks;

2. intra individual changes in faecal samples and mucosal biopsies;

3. Frequency of bowel movements;

4. Time to recurrence.

Study description

Background summary

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.

Study objective

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.

Study design

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

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-04-2011
Enrollment:	40
Type:	Actual

Ethics review

Positive opinion

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

Study results

Summary results
N/A