Ex vivo experiments to evaluate the role of medication on the colon permeability in microscopic colitis

Published: 17-09-2014
Last updated: 20-04-2024

To ex vivo assess the difference in effect of administration of NSAIDs, PPISs and SSRIs on the paracellular permeability of colon biopsies (i.e. change in trans-epithelial electrical resistance) between active, remission and non-MC patients, using...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal inflammatory conditions
Study type	Observational invasive

Summary

ID

NL-OMON41154

Source
ToetsingOnline

Brief title
The role of medication on the colon permeability in MC

Condition

- Gastrointestinal inflammatory conditions

Synonym
microscopic bowel inflammation, microscopic colitis

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Colon permeability, Medication, Microscopic Colitis, Ussing

Outcome measures

Primary outcome

The primary study outcome is the difference in colon permeability

(transpeithelial electrical resistance and FITC-permeation) caused by

administration of risk medication between the three groups (MC active, MC

remission, MC control)

Secondary outcome

n.a.

Study description

Background summary

Over the years several risk factors have been identified for MC. Medication use, especially NSAIDs, PPIs, and SSRIs, prior to diagnosis is considered a risk factor for MC development. However, the exact pathophysiological mechanism is unclear. It is hypothesized that NSAIDs, PPIs, and SSRIs may have an effect on the colon permeability, due to an idiosyncratic reaction which results in a local immune response. MC patients are considered to be susceptible hosts, prone to react on administration of abovementioned drugs. In order to test this hypothesis and to generate new insights in the pathophysiology of MC, we want to perform an Ussing chamber experiment using colon tissue samples, collected within the framework of the cohort study.

Study objective

To ex vivo assess the difference in effect of administration of NSAIDs, PPISs and SSRIs on the paracellular permeability of colon biopsies (i.e. change in trans-epithelial electrical resistance) between active, remission and non-MC patients, using the Ussing chamber system

Study design

case-control substudy

Study burden and risks

There is a 0.2% chance that a bleeding might occur, which can be stopped during the same procedure or during a new colonscopy. Moreover, there is a very small risk (<0.1%) of a bowel perforation. In case of a colonoscopy scheduled for regular care, the study risk concerns the sampling of additional colon biopsies. In theory, this may increase the chance of a procedure related complication. Excact numbers, however, are not available. If an additional endoscopic procedure has to be scheduled the burden increases due to the extra procedure and the related hospital visit. To reduce the burden for the patient, a sigmoidoscopy instead of a full colonoscopy will be performed. This is less invasive, takes less time and will be less a burden to the patient. The bowel preparation however, will remain the same, because of the potential influence of bowel preparations of the colon barrier integrity (a differen bowel prep may compromise study results).

Contacts

Public
Medisch Universitair Ziekenhuis Maastricht

P. Debyelaan 25
Maastricht 6229 HX
NL
Scientific
Medisch Universitair Ziekenhuis Maastricht

P. Debyelaan 25
Maastricht 6229 HX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In general: aged between 50-75 years, no current use of NSAIDs, PPIs or SSRIs.
* For patients in remission: positive diagnosis of microscopic, in remission under medication
* For patients with active disease: positive diagnosis of microscopic, collagenous or lymphocytic colitis; confirmed active disease due to relapse, no recent treatment for MC
* For healthy controls: no prior positive diagnosis of microscopic, collagenous or lymphocytic colitis.

Exclusion criteria

- Age below 18 years at the time of diagnosis
- Use of anticoagulants or immunosuppressive drugs
- Severe co-morbidities (including cardiopulmonary disease, portal hypertension, collagen diseases, morbid obesity, coagulation disorders and any co-morbidity hindering an endoscopic procedure)
- A previous history of any type of chronic colitis (other than MC), irritable bowel syndrome, colon carcinoma or (partial) colectomy
- A recent (last year) diagnosis of infectious diarrhea or radiation proctitis.
- Use of medication known for influencing intestinal permeability
- Excessive alcohol usage (>20 standard units per week)
- Not capable of signing an informed consent
- Defaecation diary is not matching the predefined stool frequency for the designated patient group (active, remission, control)

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-11-2015
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO

Date:	17-09-2014
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
CCMO	NL48505.068.14

Study results

Date completed:	30-05-2016
Actual enrolment:	13