The pitfall of active inflammation during surveillance colonoscopy in inflammatory bowel disease patients

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The overall objective is to assess the effectiveness of treating patients with corticosteroids prior to surveillance in order to diminish the pitfall of active inflammation.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal inflammatory conditions
Study type	Interventional

Summary

ID

NL-OMON32200

Source
ToetsingOnline

Brief title
The influence of inflammation on surveillance colonoscopy

Condition

- Gastrointestinal inflammatory conditions
- Gastrointestinal neoplasms malignant and unspecified
- Gastrointestinal therapeutic procedures

Synonym
colitis, inflammatory bowel disease (IBD)

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: dysplasia, inflammatory bowel disease corticosteroids, Surveillance

Outcome measures

Primary outcome

Primary study outcome is presence of histological inflammation of the mucosa

Secondary outcome

Secondary study paramteres are presence of other pathologic findings during endoscopy and/or in the pathology report and the management of these pathological findings. Patient characteristics that will furthermore be used in the analysis are demographic factors, like age and sex and disease characteristics like disease duration, activity and course as well as medication use.

Study description

Background summary

Patients with inflammatory bowel disease have a sufficient increased risk of developing colorectal carcinoma. Therefore surveillance for detecting early dysplasia using colonoscopy, could be performed by screening patients with colitis for neoplasia 8-10 yr after disease onset. However, there are some limits to this surveillance. One of the pittfals is active inflammation at time of surveillance. The specificity of dysplasia as a marker of precancer or cancer is controversial. Lesser degrees of inflammation are difficult to distinguish histologically from regenerative changes as a result of inflammation. Therefore surveillance cannot be performed when active mucosal inflammation is present. In that case patients first have to get treatment in order to get mucosal healing before they can get another surveillance colonoscopy. This is a burden to the patients and a stress to the endoscopy centers.

Study objective

The overall objective is to assess the effectiveness of treating patients with corticosteroids prior to surveillance in order to diminish the pitfall of active inflammation.

Study design

Randomized clinical trial

Intervention

Patients will be randomized to either two weeks daily 20 mg Prednisone and Calcium vit. D prior to surveillance colonoscopy or no treatment at all.

Patients in the treatment arm will be asked to fill out a short questionnaire in order to asses therapy adherence.

Study burden and risks

Use of prednisone is in general not associated with side effects, only in case of high dosis of longterm use. However, there are some possible side effects like fluid problems (e.g. fluid retention), psychological problems (e.g. mood swings), and skin reactions. In order to prevent osteoporosis due to longterm use of corticosteroids calcium tablets will be prescribed to the patients.
There is a potential benefit associated with participation in this study. The use of Prednison is likely to diminish the possible active mucosal inflammation which will result in mucosal healing and probably a better assesment of the biopsy material in order to detect (pre)cancer. This will prevent patients from needing a second surveillance colonoscopy due to active mucosal inflammation.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients diagnosed with either ulcerative colitis or Crohn???s disease by established criteria scheduled for surveillance colonoscopy between April 1, 2008 and March 31, 2009 in the Erasmus Medical Center will be entered into this study.

Exclusion criteria

Exclusion criteria are: diabetes, pregnancy, hypertension and known adverse reactions on earlier use of Prednisone.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-07-2008
Enrollment:	150
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Calci-chew D3
Generic name:	calcium D3
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Prednisone
Generic name:	Prednisone
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	21-03-2008
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	24-04-2008
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
EudraCT	EUCTR2008-001427-61-NL
CCMO	NL21825.078.08