Diagnostic approaches in patients suspected of Ischemic Colitis (IC)

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal signs and symptoms
Study type	Observational invasive

Summary

ID

NL-OMON33204

Source
ToetsingOnline

Brief title
DIC (= Diagnostic Ischemic Colitis)

Condition

- Gastrointestinal signs and symptoms

Synonym
Ischemic Colitis; Colon Ischemia; colonic ischemia

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: Hypoxia, Ileocolonoscopy, Ischemic Colitis, Oxygen saturation measurement

Outcome measures

Primary outcome

The evaluate the diagnostic value of mucosal oxygen saturation measurement to

endoscopy and histological examination.

Secondary outcome

To evaluate whether detection of hypoxia dependent molecular changes in the

mucosa

can be used to improve sensitivity of histological analyses.

Study description

Background summary

Ischemic colitis (IC) is the most common form of gastrointestinal ischemia, counting for half of all cases of gastrointestinal ischemia [1]. IC results from inadequate blood flow to the colon which leads to colonic inflammation. IC can present as non-gangrenous form, counting for 80-85% of cases and the gangrenous form, concerning 15-20% of cases, the latter often requiring surgery [2]. The histological findings in ischemic colon range from mucosal and submucosal hemorrhage and edema with or without ulceration and strictures to fulminant transmural gangrenous damage [1]. Non-occlusive disease is the most common cause of IC. Development of IC is associated with postoperatively after aortoiliac surgery, shock states, cardiac arrhythmia, renal failure, vasculitides, coagulopathies and vasoconstrictive medication [1,2].The whole colon can be involved, but the splenic flexure, descending colon and sigmoid are the most common sites involved in an episode of IC [1]. Currently, there is no golden standard diagnostic tool for diagnosing IC. Endoscopy and histological confirmation is the first choice diagnostic approach in patients clinically suspected of IC. However, endoscopic and histopathological findings often show nonspecific abnormalities1-2, making it difficult to diagnose IC. Visible light spectroscopy (VLS) has been introduced as a new technique which directly measures the oxygen saturation of capillary hemoglobin during endoscopy in a non-invasive manner, reflecting the adequacy of mucosal

perfusion. Friedland et al1 [3] investigated oxygen saturation levels in mucosal colon of 40 normal controls. In addition, possible markers of hypoxia, such as HIF-1 alpha, could help to improve the sensitivity of histological findings in patients suspected of IC.

Study objective

The aim of the study is to evaluate and develop new diagnostic tools for an accurate diagnosis of IC:

Primary objective: to test whether mucosal oxygen saturation has added value to endoscopy and histological examination.

Secondary objective: to test whether detection of hypoxia dependent molecular changes in the mucosa can be used to improve sensitivity of histological analyses.

Study design

A prospective cohort study conducted by the Department of Gastroenterlogy and Hepatology, Erasmus MC University Medical Center Rotterdam.

1: Mucosal oxygen saturation measurement
During the diagnostic ileocolonoscopy mucosal oxygen saturation will be measured at 7 defined points in colon (coecum, hepatic flexure, mid-transverse colon, splenic flexure, descending colon, rectosigmoid and rectum). In the presence of mucosal lesions, extra VLS measurements will be performed from the lesions and the normal appearing mucosa adjacent to it. The mucosal oxygen saturation measurement with VLS will add 5 minutes extra to the total time of 30 minutes of the ileocolonoscopy.

2: Detection of hypoxia dependent molecular changes
In each patient routine diagnostic biopsies will be taken from the endoscopically visible lesions. In addition to these routine biopsies, additional biopsies will be taken from the normal appearing mucosa adjacent to the lesions and from the mucosa at the splenic flexure and rectosigmoid. The latter biopsies will also be taken in the absence of visible lesions.
At every specified location 4 biopsies will be taken, 2 biopsies will be fixed in formaline and embedded and 2 biopsies will be snap-frozen.
The 2 biopsies fixed in formaline will be used for protein detection of hypoxia induced proteins such as HIF-1*, iFABP, or GLUT-1 using techniques such as immunohistochemistry and FISH. The 2 biopsies which are snapped frozen will be used for isolation of RNA and proteins. This will be used to detect differences in expression levels between normal mucosa, normal appearing mucosa of patients with IC and mucosal lesions of patients with IC or colitis due to other etiologies.

Study burden and risks

Patients who will participate with the investigation are not at greater risk. Colonoscopy is performed as a part of normal diagnostic approach. Due to the mucosal oxygen measurements the (ileo-)colonoscopy will last about 5 minutes longer. Mucosal biopsies will be taken for routine diagnosis from the lesions and the normal appearing mucosa adjacent to the lesion. Extra biopsies will be taken for RNA and protein isolation. This will be 4-8 additional biopsies which adds only a minor risk of perforation and prolonges the colonoscopy with 2 minutes. The total time of elongation of the colonoscopy will be 7 minutes.

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

- all patients older than 18 years old with acute onset of abdominal pain with diarrhea with or without blood loss and clinical indication for (ileo-)colonoscopy
- informed consent

Exclusion criteria

- known and recently inflammatory bowel disease in medical history
- infectious colitis
- unable to give informed consent
- age < 18 years
- pregnancy

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-02-2010
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date:	04-11-2009
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
CCMO	NL29292.078.09