Diagnostic approaches in patients clinically suspected of Ischemic Colitis (IC).

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20037

Source
NTR

Brief title
DIC

Health condition

Ischemic Colitis

Sponsors and support

Primary sponsor: Erasmus MC, University Medical Center Rotterdam, The Netherlands
Source(s) of monetary or material Support: Erasmus MC, University Medical Center Rotterdam, The Netherlands

Intervention

Outcome measures

Primary outcome

Primary endpoint:

The evaluate the diagnostic value of mucosal oxygen saturation measurement to endoscopy and histological examination.

Secondary outcome

Secondary endpoints:

1. To evaluate whether detection of hypoxia dependent molecular changes in the mucosa can be used to improve sensitivity of histological analyses;

2. To evaluate whether Doppler US of the abdomen can improve differentiation between patients with IC and other causes of abdominal pain and diarrhea.

Study description

Background summary

Background:

Ischemic colitis (IC) is the most common form of gastrointestinal ischemia, counting for half of all cases of gastrointestinal ischemia. 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. 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. 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 . 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. 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 abnormalities, 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 al. 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.

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 , iFABP, or GLUT-1 usingαdetection of hypoxia induced proteins such as HIF-1 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 population:

All patients older than 18 years old with acute onset of abdominal pain with diarrhea with or without blood loss and clinical indication for a (ileo-)colonoscopy will be asked to participate in this study. 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.

Primary and secondary outcome:

The evaluate the diagnostic value of mucosal oxygen saturation measurement to endoscopy

and histological examination.

To evaluate whether detection of hypoxia dependent molecular changes in the mucosa can be used to improve sensitivity of histological analyses.

Study objective

Primary objective:

To test whether mucosal oxygen saturation has added value to endoscopy and histological examination.

Secondary objectives:

1. To test whether detection of hypoxia dependent molecular changes in the mucosa can be used to improve sensitivity of histological analyses;

2. To test whether Doppler US of the abdomen can improve differentiation between patients with IC and other causes of abdominal pain and diarrhea.

Study design

Mucosal saturation meaurement, taking extra biopsies and Doppler US are performed during the diagnostic work up in first twee weeks.

Intervention

A prospective case-control study is being performed. No randomization or intervention is being performed.

Contacts

Public
's- Gravendijkwal 230
Aria Sana
Rotterdam 3015 CE
The Netherlands
+31 (0)10 7035821
Scientific
's- Gravendijkwal 230
Aria Sana

Rotterdam 3015 CE
The Netherlands
+31 (0)10 7035821

Eligibility criteria

Inclusion criteria

1. 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;

2. Informed consent.

Exclusion criteria

1. Known and recently inflammatory bowel disease in medical history;

2. Infectious colitis;

3. Unable to give informed consent;

4. Age < 18 years;

5. Pregnancy.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2010
Enrollment:	80
Type:	Anticipated

Ethics review

Positive opinion

Date:	18-12-2009
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	NL2029
NTR-old	NTR2146
Other	METC Erasmus MC : 2009-358
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A