

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

Gepubliceerd: 18-12-2009 Laatste bijgewerkt: 13-12-2022

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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON20037

Bron

Nationaal Trial Register

Verkorte titel

DIC

Aandoening

Ischemic Colitis

Ondersteuning

Primaire sponsor: Erasmus MC, University Medical Center Rotterdam, The Netherlands

Overige ondersteuning: Erasmus MC, University Medical Center Rotterdam, The Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary endpoint:

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

Toelichting onderzoek

Achtergrond van het onderzoek

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 Gastroenterology 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 using α detection 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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart

(Verwachte) startdatum: 01-01-2010
Aantal proefpersonen: 80
Type: Verwachte startdatum

Ethische beoordeling

Positief advies
Datum: 18-12-2009
Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2029
NTR-old	NTR2146
Ander register	METC Erasmus MC : 2009-358
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A