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Histological remission in ulcerative colitis: comparing histological activity indexes

Submission date	**Recruitment status**	[X] Prospectively registered
22/09/2015	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
24/09/2015	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
10/04/2017	Digestive System	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Ulcerative colitis (UC) is a long-term relapsing disease affecting the large intestine (colon). Its main symptoms are diarrhoea, abdominal pain and tiredness. Previously the target of treatment for these patients was clinical remission (i.e., reduced symptoms). Recently the aim of treatment changed and doctors now try to achieve normal intestinal tissue (mucosa) at endoscopy, called mucosal healing. A new treatment target has been developed called microscopic mucosal healing, where tissue samples taken from the colon (colonic biopsies) are assessed under a microscope using a scoring system and found to be normal, but it is not yet clear which scoring system to use for this. The aim of the study is to compare three commonly used scoring systems for microscopic mucosal healing in ulcerative colitis.

Who can participate?
Patients with ulcerative colitis who have already undergone a colonoscopy.

What does the study involve?
Colonic biopsies taken from the participants at a previous colonoscopy are studied. These biopsies are re-assessed by three specialist doctors using three different scoring systems. The participants do not need to have a colonoscopy again.

What are the possible benefits and risks of participating?
A single scoring system will result in a better disease outcome for ulcerative colitis patients in the future. There are no possible risks because the biopsies were taken at a previous colonoscopy.

Where is the study run from?
Radboud University Medical Center (Netherlands).

When is the study starting and how long is it expected to run for?
October 2015 to April 2016.

Who is funding the study?
Investigator initiated and funded (Netherlands).

Who is the main contact?
Tessa Römkens

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2015-1993

Study information

Scientific Title
Histological remission in ulcerative colitis: comparing histological activity indexes - an observational study

Study objectives
To compare and validate three commonly used histological scoring systems in order to define histological mucosal healing (MH).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Radboud University Medical Center, 27/08/2015, ref: 2015-1993

Study design
Single-center observational study

Primary study design
Observational

Secondary study design

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Ulcerative colitis

Interventions
Biopsies were taken during colonoscopy from patients with quiescent UC with endoscopical MH (Mayo score ≤ 1). All biopsies were reassessed by three blinded pathologists using the Gupta, Riley and Geboes histology scoring systems, and a global visual evaluation (GVE).

Intervention Type
Other

Primary outcome measure
Intra- and inter-observer variability all histological indices

Secondary outcome measures
The relationship with endoscopic mucosal healing, and the relationship between the initial judgment of the primary pathologist in all scoring systems

Overall study start date
01/10/2015

Completion date
01/04/2016

Eligibility

Key inclusion criteria
1. A colonoscopic examination between January 2014 and July 2015
2. A well-established diagnosis of UC according to clinical and histological criteria
3. Endoscopic mucosal healing throughout the entire colon according to Mayo (≤1)
4. Randomly taken colonic biopsy specimens in both left and right colon with a clear description of the microscopic features by the pathologist

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
50

Key exclusion criteria
1. Mayo endoscopic score > 1
2. Diagnosed with either Crohn’s disease or indeterminate colitis

Date of first enrolment
01/10/2015

Date of final enrolment
01/12/2015

Locations

Countries of recruitment
Netherlands

Study participating centre
Radboud University Medical Center
Nijmegen
Netherlands
6500 HB

Sponsor information

Organisation
Radboud University Medical Center (Netherlands)

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR

https://ror.org/05wg1m734

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (Netherlands)

Results and Publications

Publication and dissemination plan
The trialists intend to publish the results only and not the protocol at this stage.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request