

# Histological remission in ulcerative colitis: comparing histological activity indexes

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|----------------------------------------|---------------------------------------------------|--------------------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>22/09/2015   | <b>Recruitment status</b><br>No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>24/09/2015 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>10/04/2017       | <b>Condition category</b><br>Digestive System     | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> 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 Römken

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Mrs Tessa Römken

**Contact details**  
Radboud University Medical Center  
Department of Gastroenterology & Hepatology  
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Netherlands  
6500 HB

## Additional identifiers

**Protocol serial number**  
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

**Primary study design**  
Observational

**Study design**  
Single-center observational study

**Study type(s)**  
Diagnostic

**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  $\leq 1$ ). 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(s)**

Intra- and inter-observer variability all histological indices

**Key secondary outcome(s)**

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

**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 ( $\leq 1$ )
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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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)

### ROR

<https://ror.org/05wg1m734>

## Funder(s)

### Funder type

Other

### Funder Name

Investigator initiated and funded (Netherlands)

## Results and Publications

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Available on request