

Inclusion Criteria

1. Patients who signed the informed consent
2. Male or female patients, 18 years or older
3. Patients with chronic or intermittent, watery diarrhea of unknown etiology for more than 4 weeks
4. Patients who are eligible for complete colonoscopy according to physician's clinical criteria.

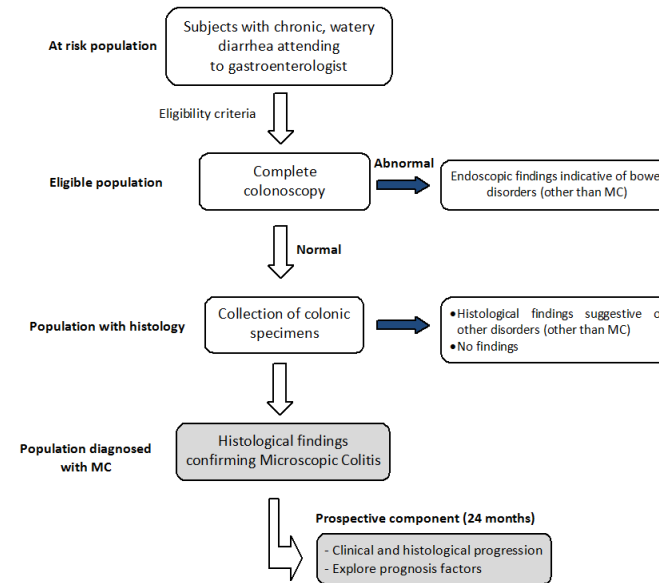
Exclusion Criteria

1. Patients with history of IBDs or any other known intestinal disease
2. Any condition that precludes the patient to undergo complete colonoscopy
3. Patients who are being treated with any investigational agent;
4. Pregnancy
5. Patients who are not willing to comply with routine clinical appointments or procedures

Laboratory Testing

- Biopsy samples must be collected into containers of 10% neutral-buffered formalin solution. There must be sufficient formalin in the container to completely cover the specimen.
- Collect two biopsies from the rectum, sigmoid, descendant, transversum, ascendant and ileum into different containers, with the respective label (RECTUM, SIGMOID...).
- Containers with samples don't need to be refrigerated but must be sent to central laboratory as soon as possible. Endoscopy report must be also sent to central laboratory.
- **Contact GEDII for transport.**

Study Flowchart



For any study related questions, please contact:

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MICRA

Title: An epidemiological study to determine the prevalence of **Microscopic Colitis** and describe its clinical and histological features among patients with symptoms of **chronic** watery diarrhea submitted to colonoscopy **Attending to the Portuguese gastroenterology setting**



Study sponsor: Grupo de Estudo da Doença Inflamatória Intestinal (GEDII)

Name of Scientific Coordinator: Prof. Fernando Magro

Primary Objective

To determine the prevalence of MC among patients who attend to the specialist appointment with symptoms of chronic, watery diarrhea of unknown etiology for more than 4 week and undergo colonoscopy.

Chronogram

Variables	All	24-month prospective part Only for patients with diagnosis of microscopic colitis							
	BSL	M3	M6	M9	M12	M15	M18	M21	M24
Date of birth	X								
Sex	X								
Height	X								
Weight	X	X	X	X	X	X	X	X	X
Smoking status	X								
Medical history	X								
Comorbidities	X								
Symptoms of diarrhea	X	X	X	X	X	X	X	X	X
Prior therapies	X								
Colonoscopy	X								X
Colonic specimen collection	X								X
Histology	X								X
Therapeutic attitude regarding MC (pharmacological/non pharmacological)		X	X	X	X	X	X	X	X
Laboratory parameters ²	X	X	X	X	X	X	X	X	X
Fecal sample (calprotectin, ECP and EPX levels)	X	X	X	X	X	X	X	X	X
Dispensing of patient diary	X ¹	X	X	X	X	X	X	X	

BSL = baseline: date of the study's first appointment; M= month; ECP= eosinophil cationic protein; EPX= eosinophil protein X

¹ The patient diary will be delivered as soon as the MC diagnosis is confirmed. The diary will be returned by the patient at each appointment and a new diary will be dispensed.

² hemoglobin, platelets, leukocytes, neutrophils, eosinophiles, basophiles, monocytes, lymphocytes, erythrocyte sedimentation rate (ESR), C-reactive protein (CRP), iron and transferrin.