Cold snare biopsies in the ileum and colon for translational studies in inflammatory bowel disease: a feasibility study

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Primary objectiveThe primary aim of this study is to assess and compare sample quality between cold-snare biopsies and standard-of-care biopsies.

Ethical review	Approved WMO
Status	Pending
Health condition type	Gastrointestinal inflammatory conditions
Study type	Interventional

Summary

ID

NL-OMON56844

Source
ToetsingOnline

Brief title
CLARIFY

Condition

- Gastrointestinal inflammatory conditions

Synonym
Inflammatory Bowel Disease

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Eigen onderzoeksfondsen van prof dr

D'Haens

Intervention

Keyword: Biopsy, Cold snare, Inflammatory Bowel Disease

Outcome measures

Primary outcome

Sample quality will be assessed based on the measure of cell yield, which quantifies the number of cells obtained in the biopsy samples. A higher cell yield typically indicates better sample quality, making it a key metric for evaluating the effectiveness of the biopsy procedures. In addition, the different cell types present in the biopsies will be analysed.

Secondary outcome

Significant intra-procedural bleeding: as objectified by the endoscopist

Post-procedural bleeding: defined as rectal blood-loss that requires re-colonoscopy: persistent bleeding (>2 days after procedure)

Perforation (objectified on cross-sectional imaging)

Infection: defined as formation of an abscess, appendicitis or peritonitis

Other adverse events related to the biopsy procedure (abdominal pain, cramps)

Patient discomfort

Study description

Background summary

Inflammatory bowel disease (IBD), including Crohn*s (CD) disease and ulcerative colitis (UC), represents a significant public health challenge and has an increasing incidence worldwide. IBD is characterized by chronic inflammation of the gastrointestinal tract, leading to a wide range of symptoms. These include

abdominal pain, diarrhea, and weight loss. IBD is associated with a substantial burden on patients* quality of life and on healthcare systems, making IBD an area of intense scientific investigation and clinical interest.
In the search to unravel the pathophysiology of IBD, researchers have turned to state-of-the-art technologies. For example, single-cell analysis and spatial transcriptomics have revolutionized the ability to unravel the complex biology of IBD. These technologies lead to the possibility to explore the characteristics of single cells within the intestinal tissue, giving in-depth insight in the disease*s pathophysiology.
However, although these technologies offer major opportunities for understanding IBD at a molecular level, they expose a critical limitation in the standard-of-care biopsy protocol used to collect intestinal samples. Current biopsy techniques are considered safe but they are not tailored for these advanced analytical methods. During the biopsy process, a considerable number of cells are inadvertently lost and the architecture is damaged, hindering the advanced research technologies. This cellular loss can lead to suboptimal results, limiting the insights gained from these cutting-edge techniques.
Therefore, a need arises for samples of improved quality that can align with the requirements of the advanced research methods. Such improvements would significantly enhance the ability to explore IBD comprehensively, shedding light on its pathogenesis. Our study aims to address this by evaluating the cold-snare biopsies, striving to provide high-quality tissue samples for the advancement of IBD research.

Cold-snare technique
Cold snaring endoscopic mucosal resection (CS-EMR) is a minimally invasive endoscopic procedure and is designed to remove and analyze abnormal or pre-cancerous tissue from the gastrointestinal tract (2). CS-EMR combines submucosal fluid injection and the use of a cold snare, a specialized cutting instrument, which, as the name implies, does not rely on thermal energy for tissue removal. Instead, it employs a snare-like mechanism to remove targeted lesions with precision, often in a single session.
A lot of research has been performed to define the safety of CS-EMR in the scope of polypectomy procedures. For example, a meta-analysis performed by Ortigão and colleagues in 2021 analyzed the adverse event rate of CS-EMR of polyps bigger than 10mm, reporting an adverse event range <1% (cumulative n=577) (3). In addition, two randomized controlled trials that compared CS-EMR to other polypectomy procedures reported post-procedural bleeding of 0% and 0.8% (n= 83; n=135) (4, 5).
Beyond polypectomy, there is a notable absence of data comparing sample quality between cold-snare biopsies and the standard-of-care biopsy protocol.

Study objective

Primary objective
The primary aim of this study is to assess and compare sample quality between

cold-snare biopsies and standard-of-care biopsies.

Study design

This prospective, single-center pilot study aims to evaluate sample quality of cold-snare biopsies. The study includes three phases: rectal biopsy, colon biopsy, and terminal ileum biopsy. After confirming the feasibility of the cold-snare biopsy procedure in the rectum, the procedure will be extended to the colon and terminal ileum. This phased approach is chosen, considering that perforations in the rectum are typically less problematic due to the retroperitoneal position, ensuring a methodical safety assessment. The study has a 30-day follow-up period.

Intervention

The intervention is endoscopic sampling of the rectum, colon and ileum. The only deviation from routine clinical practice is the cold snare biopsy of the specific segment.

Study burden and risks

Patients will not benefit from this study at the individual level.
Patients who participate will deliver standard-of-care biopsies and undergo a cold-snare biopsy during routine endoscopy. The potential risk of participation is low. Collection of the standard-of-care biopsies during endoscopy carries an established risk (perforation or bleeding) of <1:10.000 procedures (endoscopy with biopsies). In the current study, an additional cold-snare biopsy is taken. Different studies have been performed to assess the safety of cold-snare techniques and the risk of adverse events is considered to be low (<1%) in the context of polypectomy procedures.
Most complications can be treated (coagulopathy/clipping) during the colonoscopy. occasionally, an additional endoscopy has to be performed. In seldom case the patient needs to be hospitalized for blood transfusion, antibiotics or surgery. Patients are informed about all risks in the informed consent form.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Inflammatory Bowel Disease (IBD) (Crohn*s disease (CD) or ulcerative colitis (UC)) patients who are planned to undergo a routine IBD colonoscopy with the collection of biopsies for disease activity assessment; >=18 years old; active disease (defined as Mayo>1 for UC or SES-CD>2 for CD); ability to provide informed consent.

Exclusion criteria

Complete remission; history of colonic perforation during endoscopic procedures; active use of anticoagulant medications; familial history of bleeding disorders; known individual bleeding disorders; suspicion of dysplasia or colorectal carcinoma.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	23-06-2024
Enrollment:	34
Type:	Anticipated

Medical products/devices used

Generic name:	Cold snare
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	13-06-2024
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL85756.018.24