

Patient Information Sheet for Participation in a Research Project

Impact of Artificial Intelligence on the Detection of Colonic Dysplasia in Patients with Inflammatory Bowel Disease

Date: 24/04/2023

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Version 1 (Date: 24/04/2023)

Sponsor: Vall d'Hebron Research Institute (VHIR)

Study Title: Impact of Artificial Intelligence on the Detection of Colonic Dysplasia in Patients with Inflammatory Bowel Disease

Code: PR(AG)237/2023

Sponsor: Crohn's and Colitis Care Unit (UACC), Vall d'Hebron University Hospital

Principal Investigator: Xavier Serra Ruiz

Center: Vall d'Hebron University Hospital, Digestive Diseases Department – UACC

INTRODUCTION

You are being invited to participate in a research study approved by a Research Ethics Committee. Please read this information carefully so that you can decide whether or not to participate. You may ask questions at any time and consult anyone you consider appropriate before making your decision.

VOLUNTARY PARTICIPATION AND RIGHT TO WITHDRAW

Your participation is entirely voluntary. You may refuse to participate or withdraw your consent at any time without affecting your relationship with your physician or your medical care.

Patients with Crohn's disease and ulcerative colitis have an increased risk of developing premalignant lesions and colorectal cancer. Colonoscopy is the preferred method for screening these lesions. Chromoendoscopy improves lesion detection and allows targeted biopsies. The usefulness of artificial intelligence in this setting has not yet been studied, although promising results have been observed in patients without inflammatory bowel disease through improved polyp detection.

OBJECTIVE

The main objective of this study is to determine the usefulness of artificial intelligence in dysplasia screening for patients with inflammatory bowel disease.

BENEFITS

You may not receive a direct benefit from participating in this study. However, the results may benefit future patients and contribute to a better understanding and treatment of this disease.

STUDY PROCEDURES

Colonoscopy is a medical procedure used to examine the colon and rectum for polyps, cancer, and other diseases. During the procedure, a flexible endoscope is inserted through the anus and advanced through the colon. Biopsies may be taken and polyps removed if necessary. Colonoscopy is performed under sedation and usually lasts 30–60 minutes.

You will undergo a screening colonoscopy as part of the routine follow-up of your ulcerative colitis or Crohn's disease. During the same procedure, both study techniques (chromoendoscopy and artificial intelligence) will be applied. Neither technique involves risks beyond those of colonoscopy itself. Sedation and procedure time will be somewhat longer because both techniques will be performed during the same examination. Data from your medical record will also be collected.

RISKS AND DISCOMFORTS

Potential risks of colonoscopy include:

- Bleeding.
- Perforation of the colon or rectum.
- Infection.
- Allergic reactions to medications or sedatives.
- Abdominal pain or cramping.
- Gas retention and abdominal distension.
- Cardiac or respiratory complications related to sedation.
- Other uncommon risks, including reactions to anesthesia.

DATA PROTECTION

The sponsor and study center will ensure the confidentiality of your personal data in accordance with national and European data protection regulations. Please refer to Appendix 1 for additional information.

INFORMED CONSENT

I, _____ (patient name), confirm that:

- I have read the information sheet provided to me.
- I have had the opportunity to ask questions.
- I have discussed the study with the investigator.
- I understand that participation is voluntary.
- I understand that I may withdraw at any time without explanation and without affecting my medical care.

I freely agree to participate in this study and confirm that I have read Appendix 1 and agree with its contents.

I agree to be contacted in the future if additional data collection is considered necessary:

Yes ___ No ___

Participant Signature: _____

Investigator Signature: _____

Date: ____/____/____

I wish to be informed of any research findings that may be relevant to my health or that of my relatives: Yes ____ No ____

Contact telephone number or e-mail: _____

I accept the future use of my data for unrelated research projects: Yes ____ No ____

REFUSAL OR WITHDRAWAL OF INFORMED CONSENT

I, _____, or my representative (if applicable), refuse or withdraw consent to participate in this study. From the date of withdrawal, no additional medical data will be collected, without affecting the retention of data already obtained before withdrawal.

Date of refusal/withdrawal: _____

Signature: _____