Artificial intelligence in the characterization of colorectal polyps: A prospective study in a clinical setting using CAD EYE®

INFORMED CONSENT

Elisa Gravito-Soares, Marta Gravito-Soares, Pedro Amaro

October 29th, 2020

Artificial intelligence in the characterization of colorectal polyps: A prospective study in a clinical setting using CAD EYE®

Elisa Gravito-Soares, Marta Gravito-Soares, Pedro Amaro

Gastroenterology Department, Centro Hospitalar e Universitário de Coimbra, E.P.E., Coimbra, Portugal

INFORMATION FORM AND

INFORMED CONSENT

TITLE OF THE RESEARCH PROJECT:

Artificial intelligence in the characterization of colorectal polyps: A prospective study in a clinical setting using CAD EYE®

STUDY PROMOTER: Dr Pedro Amaro

RESEARCH COORDINATOR	Pedro Nuno Abrantes Amaro
STUDY CENTRE	Gastroenterology Department, Centro Hospitalar e Universitário de Coimbra, E.P.E.
PRINCIPAL INVESTIGATORS	Elisa Gravito-Soares, Marta Gravito-Soares, Pedro Amaro
ADRESS	Praceta Prof. Mota Pinto, 3000-075 Coimbra
PHONE NUMBER	(+351)239400483
FAX NUMBER	(+351)239701517

PATIENT'S NAME (Press letter) _____

Participants are voluntarily invited to be included in this study, in which a colonoscopy will be performed with possible endoscopic resection of colorectal polyps identified, since there are no contraindications for its performance. An auxiliary diagnostic tool will be added to the colonoscopy itself in order to allow the optimization of detection and optical characterization of colorectal polyps, without obviating the recovery

of resected colorectal polyps for histopathological study. This tool is incorporated in the endoscopic software and when activated, acts in real time, during the colonoscopy performance.

This procedure, so-called **informed consent**, describes the purpose of the study, the procedures to be performed and the possible benefits and associated risks. The participation of the patient may contribute to improve the detection ability of colorectal polyps, considered as precursors of colorectal cancer, improving the reduction of its incidence, prevalence and mortality, as well as the risk of interval colorectal cancer.

Optical diagnosis may obviate the most endoscopic resection of colorectal polyps, especially small polyps, allowing the reduction of histopathology-related costs, as well as the complications associated with this therapeutic procedure (bleeding, post-polypectomy coagulation syndrome and perforation).

Participants will receive a copy of this Informed consent to review and seek advice from family and friends (if desired). Investigators and other members of research team will clarify any questions about the consent form. Once the study is understood and there is no doubt about it, the participant should make the decision to participate or not. If the patient agrees to participate, he/she will be asked to sign and date this form. After the participant and investigator's signatures have been obtained, a **copy** of signed informed consent will be given to the participant. In case of no participation, there will be no penalty for the health care provided to the patient.

1. GENERAL INFORMATION AND OBJECTIVES OF THE STUDY

This study will take place at the **Gastroenterology Department** of the **Centro Hospitalar e Universitário de Coimbra, E.P.E.** (colonoscopy and possible endoscopic resection of colorectal polyps identified). The objective is to evaluate the impact of applying a new artificial intelligence tool in the detection and optical characterization of colorectal polyps. This is a unicentric prospective observational cohort study with no changes in terms of medication or routine treatments other than bowel preparation to perform the colonoscopy according to the participant comorbidities.

This study was approved by the Ethics Committee of the Faculty of Medicine of the University of Coimbra (FMUC) in order to ensure the rights protection, safety and wellbeing of all included participants and to guarantee public proof of such protection.

In order to ensure participants' safety, the **surveillance** and **support** from a **Gastroenterologist** will be provided, before, during and after the diagnostic colonoscopy with or without therapeutic actions.

This study aims to assess the impact of the application of a new artificial intelligence tool – CAD EYE® – on the detection and optical characterization of colorectal polyps and consequent clinical (reduction of the incidence, prevalence, mortality and the risk of interval colorectal cancer, as well as the reduction of

endoscopic resection-associated morbidity of colorectal polyps) and economic advantages (reducing of histopathology-related costs).

2. PROCEDURES AND STUDY DESIGN

2.1. Procedures

A Gastroenterologist of the study will conduct a review of medical history and chronic medication from all participants. After the patient accepts to participate in this study, the colonoscopy will be performed with the possibility of endoscopic resection of colorectal polyps, during which a new artificial intelligence technology will be applied – CAD EYE®.

2.2. Schedule of hospital visits and duration

This study consists of a single hospital visit to perform the colonoscopy with possible endoscopic resection of colorectal polyps, after an anterograde bowel preparation. The application of this new artificial intelligence technology – CAD EYE® takes place during colonoscopy in real time, with no additional costs or risks. In case of non-use of this device, post-polypectomy surveillance guidance will be the same, including the evaluation in a Gastroenterology appointment to define the appropriate endoscopic surveillance intervals.

2.3. Data processing

Data collected from the clinical history, diagnostic and/or therapeutic colonoscopy, artificial intelligence technology and histopathological study will be submitted to a statistical analysis, with anonymity guarantee in all phases of the study.

3. RISKS AND POTENTIAL DRAWBACKS FOR THE PARTICIPANT

There is no risks arising from participation in this study, from the additional use of this new artificial intelligence technology – CAD EYE®. The risks associated with the performance of diagnostic and/or therapeutic colonoscopy and its anterograde bowel preparation are discriminated in the additional informed consent specially designed for this purpose, and are the same regardless of whether or not artificial intelligence technology is used to aid diagnosis.

4. POTENTIAL BENEFITS

This study has the advantage of studying colorectal polyps, as premalignant lesions with potential to develop colorectal cancer. Artificial intelligence technology will add gains in clinic (reduction of incidence,

prevalence, mortality and risk of interval colorectal cancer, as well as endoscopic resection-associated morbidity of colorectal polyps) and economy (reduction of histopathology-related costs). So, this new diagnostic tool will improve clinical health care offered for patients in similar conditions.

5. NEW INFORMATIONS

Participants will be informed of any new information that may be relevant to colorectal polyps' condition or influence in their willingness to continue participating in the study.

6. VOLUNTARY PARTICIPATION/ABANDONMENT

Participants are entirely free to accept or refuse to participate in this study, and may withdraw their consent at any time with no any consequence, penalty or loss of benefit and without compromising the relationship between participants and medical team involved in this study. Participants should inform the investigator of their decision to withdraw consent.

Study investigator may decide to end patients' participation, in case of not be in their health best interest to continue in this study. In addition, patients' participation may also be ended in case of no follow the study plan, by administrative decision or decision of the Ethics Committee. Study investigator will notify the participants if one of these conditions is met.

7. CONFIDENTIALITY

Without violating confidentiality rules, auditors and regulatory authorities will be permitted access to medical records to verify the performed procedures and the information obtained from the study in accordance with applicable laws and regulations. Participants' data will be kept confidential and anonymized and in case of study publication, their identity will remain confidential.

By signing this informed consent, participants authorize this conditional and restricted access.

Participants may also exercise their right to access the information at any time, having access to their medical information directly or through study investigators, and have the right to object to the data transmission that is covered by professional confidentiality.

Identifying medical records and the signed informed consent form will be checked for study purposes by the sponsor and/or representatives of the sponsor, and for regulatory purposes by the sponsor and/or representatives of the sponsor and regulatory agencies in other countries. The Ethics Committee responsible for this study may request access to participants' medical records to ensure that the study is being conducted in accordance with the protocol. Absolute confidentiality cannot be guaranteed due to the need for transmission of information to these parts.

By signing this informed consent form, participants allow that their medical data be verified, processed and reported as necessary for legitimate scientific purposes.

Confidentiality and processing of personal data

Personal data of study participants, including medical or health information, collected or created as part of the study (such as medical data or test results), shall be used for carried out the study, including for scientific research related to the condition under study.

In giving consent to participate in this study, the participants' information, including clinical data, shall be used as follows:

1. The sponsor, investigators and others involved in the study will collect and use participants' personal data for the purposes described above.

2. Study data associated with participants' initials or other code with no direct identification (and no participants' name) will be communicated by researchers and others involved in the study to the study sponsor, who will use them for the purposes described above.

3. Study data associated with participants' initials or other code with no direct identification may be communicated to national and international health authorities.

4. Participants' identity will not be revealed in any reports or publications resulting from this study.

5. All persons or entities with access to participants' personal data are subject to professional confidentiality.

6. By giving consent to participate in this study, participants authorize the sponsor or study monitoring companies specifically contracted for this purpose and their employees and/or health authorities, to access the data contained in clinical files, to check the information collected and recorded by the investigators, namely to ensure data accuracy concerning participants and to guarantee that the study is being carried out correctly and the obtained data are reliable.

7. Considering law terms, participants have the right, through one of the study investigators, to request access to their data, as well as to request the rectification of their identification data.

8. Participants also have the right to withdraw their consent at any time by notifying the investigator, implying the end of participation in the study. However, non-identifiable data collected or created as a part of the study until that time may continue to be used for the purpose of the study, in particular to maintain the scientific integrity of the study, not being removed their medical data from the study file.

9. If participants do not give their consent, by signing this document, their participation in this study is not allowed. If and until the given consent is not withdrawn, it remains valid.

8. COMPENSATION

This study is the initiative of the investigator and therefore patient participation is requested without any financial compensation for its implementation, as is also the case with the investigators and the Study Centre.

9. CONTACTS

If any questions regarding participants' rights in this study, please contact the Ethics Committee:

The Ethics Committee of the FMUC,

Azinhaga de Santa Comba, Celas – 3000-548 Coimbra

Phone number: (+351)239857707

e-mail: comissaoetica@fmed.uc.pt

In case of any question about this study, please contact:

Elisa Gravito-Soares, Marta Gravito-Soares

Gastroenterology Department, Centro Hospitalar e Universitário de Coimbra, E.P.E.

Praceta Prof. Mota Pinto, 3000-075 Coimbra, Portugal

Phone number: (+351)239400483

THIS INFORMED CONSENT FORM SHOULD NOT BE SIGNED WITHOUT THE PARTICIPANTS HAVING BEEN GIVEN THE OPPORTUNITY TO ASK AND RECEIVE SATISFACTORY ANSWERS TO ALL THEIR QUESTIONS.

INFORMED CONSENT

In accordance with the Helsinki Declaration of the World Medical Association and its updates, the participants declare that:

1. Read this informed consent form and accept to participate in this study on a voluntary basis.
2. Receive all the study information about its nature, objectives, risks, likely duration as well as what is expected from the participant.
3. Have the opportunity to ask questions about the study and have understood the answers and the given information.
4. At any time can ask further questions to the study investigator and receive information about the study development. The investigator in charge of the study will give to participants all important information that comes up during the study that may change their willingness to continue to participate.
5. Agree to use information, including medical history and treatments with strict respect for medical secrecy and anonymity. Participants data will be kept strictly confidential. The authorization for consult their data will be given only to persons designated by the promoter and representatives of regulatory authorities.
6. Agree to follow all instructions given during the study and to cooperate with the investigator and to inform him/her immediately of changes in health and well-being and of all unexpected and unusual symptoms that occur.
7. Agree to use the results of the study for scientific purposes only and, in particular, I accept that these results will be disclosed to the relevant health authorities.
8. Accept that data generated during the study will be computerized by the sponsor or another person designated by him.
9. Can exercise their right of rectification and/or opposition.
10. Are free to withdraw from the study at any time, without having to justify their decision and without compromising the quality of health care provided. In addition, the investigator has the right to decide on their early withdrawal from the study, with information to the participants about the withdrawal cause.
11. Have been informed that the study may be interrupted by decision of the investigator, sponsor or regulatory authorities.

***Participants' name*_____**

***Signature :* _____ *Date:*_____/_____/____**

***Witness's name / Legal Representative:* _____**

***Signature:* _____ *Date:*_____/_____/____**

The investigator confirms that have explained to the above-mentioned participant the nature, objectives and potential risks of the above-mentioned study.

***Invetigator's name:*_____**

***Signature:* _____ *Date:*_____/_____/____**