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Title: Detection of Colonic Polyps Via a Large Scale Artificial Intelligence (AI) System

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Clinical Study Protocol Synopsis

Detection of Colonic Polyps Via a Large Scale Artificial Intelligence (AI) System

Study Objective:
To measure the accuracy of the real-time AI system in detecting colorectal polyps

Background:
Adenomatous Polyps detection is ultimate goal of screening colonoscopy, the gold standard for colorectal cancer detection yet over 10% of large adenomatous polyps are missed. The use of computerized detection software (as the case in radiology) could potentially improve adenoma detection rate (ADR). A 1% increase in ADR is associated with a 3% reduction in the risk of post-colonoscopy colorectal cancer. The propostes system is a real time detection device designed to draw the Colonscopists attention to potential lesions.

The device system is based on an Artificial Intelligence algorithm to automatically annotate findings in real-time that are suggestive of lesions. It is installed on a standalone cart including a dedicated computer and screen that receives the real time video from the Colonosocopy system.
Findings are displayed side-by-side on the dedicated EVA screen annotated (visual feedback) and the user is also notified (audio feedback).

Study Design Prospective, single center, open-label, exploratory study.

Study Endpoints
Primary endpoints:
(a) number of additional polyps detected by DEEP2 in real time
(b) safety.

Secondary endpoints:
(c) Polyp detection rate (i.e. percentage of colonoscopies where > 1 polyps were detected);
(d) Rate of false alarms per colonoscopy (False positive and false negative);
(e) User experience on a 5-point scale.

Study Population: 100Consecutive scheduled screening colonoscopy patients meeting eligibility criteria.

Eligibility Criteria

Inclusion criteria
1.   Consecutive patients undergoing routine colonoscopy in an ambulatory non-urgent setting will be eligible to participate in the study.
2.   Informed consent.
3.   Not participating in other clinical study.

Exclusion criteria
1.   Previous GI surgery involving the colon or rectum.
2.   Known Pre-diagnosis of CRC.
3.   Previous history of IBD.
4.   High suspicion or diagnosis of genetic polyposis syndromes
5.   Known pathologic finding in previous CT scan or other imaging modalities

Statistical Plan
Sample Size
Three (3) experienced (performed > 250 Colonoscopy per year) will perform a total of 100 colonoscopies (100 patients). Each Colonoscopist will perform at least 25 procedures (25/100).

Statistical Analysis
Since this is a single arm open label study without a control arm, only descriptive statistics will be used to define baseline demographic characteristics of patients and of the outcomes. Patients' data and clinical parameters are given as means with 95% CI.

Methodology
All procedures will be performed during a single session:

Screening
•   Eligible patients that agree to participate in the study will sign the related informed consent form in addition to the regular consent form for the colonoscopy.

Procedure
•   Screening colonoscopy according to standard clinical practice using the standard equipment. The Colonoscopists is informed by AI system side-by-side real-time display and audio notifications on findings suggestive of lesions. Highlighted findings by the System will be inspected by the Colonoscopists in real-time, the ultimate diagnosis of the lesion (polyp or false alarm) and decision on appropriate treatment (resection or not and resection technique) will remain in the responsibility of the colonoscopist alone. A nurse coordinator will record in real-time the results of these assessment on case report forms (number of detected polyps, additional polyps detected by the system that where missed by the colonoscopist, false alarm).
•   At the end of each procedure, the colonoscopist user experience will be evaluated using a scale of 1-5, the user will be asked "on a scale of 1-5 how useful did you find the system in this procedure".

Follow-up:
•   Patient safety follow up will be performed as regularly practiced at the digestive diseases institute, each adverse event will be registered in case report form.

Study duration

The overall enrollment period is expected to last approximately 3 months (assuming recruitment rate of 1 patient per day), but may extend for up to one year.

Training
•   All experienced physician will have onboarding training
•   Observers will be trained on their role and questionnaire

Statistical methods

Cohorts:
 For performance and safety: The ITT population will include all enrolled subjects.

Regulatory compliance:
This study will be subject for EC and Israeli Ministry of Health approval in accord with the Israeli MoH Clinical Trial Requirements (NOHAL 14, 2016). This Investigator Initiated study will comply with GCP (ISO14155) where the Investigators assumed the GCP responsibilities of the sponsor and investigator.
The study will be submitted to the ethical review board of Shaare Zedek Medical Center. The study will be conducted in accordance with the Good Clinical Practice guidelines of the International Conference on Harmonization and the provisions of the Declaration of Helsinki.