ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
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Study Identification

Unique Protocol ID:	METC2021-3036
Brief Title:	Real-time Diagnosis of Diminutive Colorectal Polyps Using AI (COMET-OPTICAL)
Official Title:	Real Time Computer-aided Diagnosis (CADx) of Diminutive Colorectal Polyps Using Artificial Intelligence
Secondary IDs:	

Study Status

Record Verification:	April 2022
Overall Status:	Recruiting
Study Start:	August 20, 2021 [Actual]
Primary Completion:	September 2022 [Anticipated]
Study Completion:	December 2022 [Anticipated]

Sponsor/Collaborators

Sponsor:	Maastricht University Medical Center
Responsible Party:	Sponsor
Collaborators:	Catharina Ziekenhuis Eindhoven Eindhoven University of Technology

Oversight

U.S. FDA-regulated Drug:	No
U.S. FDA-regulated Device:	No
Unapproved/Uncleared Device:	No
U.S. FDA IND/IDE:	No
Human Subjects Review:	Board Status: Approved Approval Number: METC 2021-3036 Board Name: Medical Ethical Committee azM / UM Board Affiliation: Maastricht University Medical Center Phone: 03143 3876009 Email: secretariaat.metc@mumc.nl Address: P. Debyelaan 25

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Data Monitoring: No

FDA Regulated Intervention: No

Study Description

Brief Summary: Correct endoscopic prediction of the histopathology and differentiation between benign, pre-malignant, and malignant colorectal polyps (optical diagnosis) remains difficult. Artificial intelligence has great potential in image analysis in gastrointestinal endoscopy. Aim of this study is to investigate the real-time diagnostic performance of AI4CRP for the classification of diminutive colorectal polyps, and to compare it with the real-time diagnostic performance of commercially available CADx systems.

Detailed Description: Correct endoscopic prediction of the histopathology and differentiation between benign, pre-malignant, and malignant colorectal polyps (optical diagnosis) remains difficult. Despite additional training, even experienced endoscopists continue to fail meeting international thresholds set for safe implementation of treatment strategies based on optical diagnosis.

Multiple machine learning techniques - computer-aided diagnosis (CADx) systems - have been developed for applications in medical imaging within colonoscopy and can improve endoscopic classification of colorectal polyps.

Aim of this study is to explore the feasibility of the workflow using AI4CRP (a CNN based CADx system) real-time in the endoscopy suite, and to investigate the real-time diagnostic performance of AI4CRP for the diagnosis of diminutive (<5mm) colorectal polyps. Secondary, the real-time performance of commercially available CADx systems will be investigated and compared with AI4CRP performance.

Conditions

Conditions: Colorectal Neoplasms
Colorectal Polyp

Keywords: Artificial intelligence
Computer-aided diagnosis (CADx)

Study Design

Study Type: Observational

Observational Study Model: Cohort

Time Perspective: Prospective

Biospecimen Retention:

Biospecimen Description:

Enrollment: 105 [Anticipated]

Number of Groups/Cohorts: 1

Groups and Interventions

Groups/Cohorts	Interventions
Gastroenterology patients Patient receiving a colonoscopy because of regular care will be considered eligible for inclusion if at least one diminutive colorectal polyp is encountered during the colonoscopy. Patients receive an endoscopic procedure in the context of the Dutch national screening program, because of gastrointestinal symptoms, or because of follow-up of previously diagnosed bowel diseases. Colonoscopies will be executed using Fujifilm endoscopy systems (Fujifilm® Corporation, Tokyo, Japan), using Pentax endoscopy systems (Pentax Medical®, Hamburg, Germany), and using Olympus endoscopy systems (Olympus®, Tokyo, Japan).	Device: Computer-aided diagnosis (CADx) systems -AI4CRP (artificial intelligence for colorectal polyps), a CNN based computer-aided diagnosis system for diagnosis of colorectal polyps (COMET-OPTICAL research group); -CAD EYE, a computer-aided diagnosis system for diagnosis of colorectal polyps (Fujifilm® Corporation, Tokyo, Japan). Other Names: • AI4CRP, artificial intelligence for colorectal polyps (COMET-OPTICAL research group) • CAD EYE (Fujifilm® Corporation, Tokyo, Japan)

Outcome Measures

Primary Outcome Measure:

1. Technical feasibility of real-time use of AI4CRP.
   The technical feasibility of real-time use of AI4CRP in the endoscopy suite regarding a proper reception of the video output from the local endoscopy processor towards AI4CRP (in high definition quality, without any delays in time).

   [Time Frame: 6 months]
2. User interface feasibility of real-time use of AI4CRP.
   The user interface feasibility of real-time use of AI4CRP in the endoscopy suite regarding a correct alignment of the user interface of AI4CRP with the video output from the local endoscopy system (resizing image pixels and anonymization).

   [Time Frame: 6 months]
3. The diagnostic accuracy of AI4CRP per image modality (HDWL, BLI, LCI, i-scan).
   The real-time diagnostic accuracy of AI4CRP per image modality (HDWL, BLI, LCI, i-scan). Diagnostic accuracy defined as the percentage of correctly optically diagnosed colorectal polyps.

   [Time Frame: 1 year]
4. The sensitivity of AI4CRP per image modality (HDWL, BLI, LCI, i-scan).
   The real-time sensitivity of AI4CRP per image modality (HDWL, BLI, LCI, i-scan).

   [Time Frame: 1 year]
5. The specificity of AI4CRP per image modality (HDWL, BLI, LCI, i-scan).
   The real-time specificity of AI4CRP per image modality (HDWL, BLI, LCI, i-scan).

   [Time Frame: 1 year]
6. The negative predictive value of AI4CRP per image modality (HDWL, BLI, LCI, i-scan).
   The real-time negative predictive value of AI4CRP per image modality (HDWL, BLI, LCI, i-scan).

   [Time Frame: 1 year]
7. The positive predictive value of AI4CRP per image modality (HDWL, BLI, LCI, i-scan).
   The real-time positive predictive value of AI4CRP per image modality (HDWL, BLI, LCI, i-scan).

[Time Frame: 1 year]

8. The Area Under ROC Curve (AUC) of AI4CRP per image modality (HDWL, BLI, LCI, i-scan).
   The real-time Area Under ROC Curve (AUC) of AI4CRP per image modality (HDWL, BLI, LCI, i-scan).

   [Time Frame: 1 year]

Secondary Outcome Measure:

9. The diagnostic accuracy of AI4CRP per polyp.
   The real-time diagnostic accuracy of AI4CRP per polyp (comprising the combination of different imaging modalities).

   [Time Frame: 1 year]

10. The sensitivity of AI4CRP per polyp.
    The real-time sensitivity of AI4CRP per polyp (comprising the combination of different imaging modalities).

    [Time Frame: 1 year]

11. The specificity of AI4CRP per polyp.
    The real-time specificity of AI4CRP per polyp (comprising the combination of different imaging modalities).

    [Time Frame: 1 year]

12. The negative predictive value of AI4CRP per polyp.
    The real-time negative predictive value of AI4CRP per polyp (comprising the combination of different imaging modalities).

    [Time Frame: 1 year]

13. The positive predictive value of AI4CRP per polyp.
    The real-time positive predictive value of AI4CRP per polyp (comprising the combination of different imaging modalities).

    [Time Frame: 1 year]

14. The Area Under ROC Curve (AUC) of AI4CRP per polyp.
    The real-time Area Under ROC Curve (AUC) of AI4CRP per polyp (comprising the combination of different imaging modalities).

    [Time Frame: 1 year]

15. The diagnostic accuracy of CAD EYE in BLI mode, per polyp.
    The real-time diagnostic accuracy of CAD EYE in BLI mode, per polyp.

    [Time Frame: 1 year]

16. The sensitivity of CAD EYE in BLI mode, per polyp.
    The real-time sensitivity of CAD EYE in BLI mode, per polyp.

    [Time Frame: 1 year]

17. The specificity of CAD EYE in BLI mode, per polyp.
    The real-time specificity of CAD EYE in BLI mode, per polyp.

    [Time Frame: 1 year]

18. The negative predictive value of CAD EYE in BLI mode, per polyp.
    The real-time negative predictive value of CAD EYE in BLI mode, per polyp.

    [Time Frame: 1 year]

19. The positive predictive value of CAD EYE in BLI mode, per polyp.
    The real-time positive predictive value of CAD EYE in BLI mode, per polyp.

    [Time Frame: 1 year]

20. The Area Under ROC Curve (AUC) of CAD EYE in BLI mode, per polyp.
    The real-time Area Under ROC Curve (AUC) of CAD EYE in BLI mode, per polyp.

    [Time Frame: 1 year]

21. The diagnostic accuracy of AI4CRP per patient.
    The real-time diagnostic accuracy of AI4CRP per patient (in case of multiple polyps per patient).

    [Time Frame: 1 year]

22. The diagnostic accuracy of CAD EYE per patient.
    The real-time diagnostic accuracy of CAD EYE per patient (in case of multiple polyps per patient).

    [Time Frame: 1 year]

23. The localization score of AI4CRP.
    The localization score of AI4CRP regarding the number of images in which the heatmap produced by AI4CRP pointed out the area of interest (scale: correct, incorrect, or partly correct area of interest).

    [Time Frame: 1 year]

24. The difference in diagnostic accuracy of endoscopists per polyp before and after AI.
    The difference in real-time diagnostic accuracy of endoscopists per polyp before and after AI.

    [Time Frame: 1 year]

25. The difference in sensitivity of endoscopists per polyp before and after AI.
    The difference in real-time sensitivity of endoscopists per polyp before and after AI.

    [Time Frame: 1 year]

26. The difference in specificity of endoscopists per polyp before and after AI.
    The difference in real-time specificity of endoscopists per polyp before and after AI.

    [Time Frame: 1 year]

27. The difference in negative predictive value of endoscopists per polyp before and after AI.
    The difference in real-time negative predictive value of endoscopists per polyp before and after AI.

    [Time Frame: 1 year]

28. The difference in positive predictive value of endoscopists per polyp before and after AI.
    The difference in real-time positive predictive value of endoscopists per polyp before and after AI.

    [Time Frame: 1 year]

29. The agreement in surveillance interval based on optical diagnosis and histopathology.
    The agreement in surveillance interval based on optical diagnosis of diminutive colorectal polyps and histopathology of small and large colorectal polyps, compared to the surveillance interval based on histopathology of all colorectal polyps (diminutive, small, and large).

    [Time Frame: 1 year]

Eligibility

Study Population:	Patient receiving a colonoscopy because of regular care will be considered eligible for inclusion if at least one diminutive colorectal polyp is encountered during the colonoscopy. Patients receive an endoscopic procedure in the context of the Dutch national screening program, because of gastrointestinal symptoms, or because of follow-up of previously diagnosed bowel diseases.
Sampling Method:	Non-Probability Sample
Minimum Age:	18 Years
Maximum Age:	
Sex:	All
Gender Based:	No
Accepts Healthy Volunteers:	No
Criteria:	Inclusion Criteria:

- Age >18 years;
- Patients with at least one colorectal polyps encountered during colonoscopy;
- Patients referred for a colonoscopy by the Dutch bowel cancer screening program, patients undergoing a colonoscopy for endoscopic surveillance, or patients undergoing a colonoscopy because of complaints;
- Written informed consent.

Exclusion Criteria:

- Patients with prior history of inflammatory bowel diseases (IBD) or polyposis syndromes;
- Patients with inadequate bowel preparations after adequate washing, suctioning, and cleaning manoeuvres have been performed by the endoscopist;
- Patients undergoing an emergency colonoscopy;
- Written objection in the patient file for participation in scientific research.

Contacts/Locations

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IPDSharing

Plan to Share IPD: Undecided
A data sharing plan is not yet decided on.

References

Citations:

Links:	
Available IPD/Information:	