Diagnostic Performance of a Convolutional Neural Network for Diminutive Colorectal Polyp Recognition

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26387

Source
Nationaal Trial Register

Brief title
POLAR

Health condition

Colorectal cancer, colorectal polyps

Sponsors and support

Primary sponsor: Amsterdam UMC, location AMC
Source(s) of monetary or material Support: The collaboration project is co-funded by the PPP Allowance made available by Health~Holland, Top Sector Life Sciences & Health, to the Dutch Digestive Disease Foundation to stimulate public-private partnerships (TKI 18-01); the European Regional Development Fund region Northern-Netherlands (UP-18-00565); and the province of Friesland. ZiuZ Medical B.V provided research equipment on loan for this study.

Intervention

Outcome measures

Primary outcome

The primary outcome of the study is the accuracy of the CAD-CNN system for predicting histology of diminutive colorectal polyps (1-5mm) compared with the accuracy of the prediction of the endoscopist. Both the CAD-CNN system and the endoscopist will use NBI for their predictions.

Accuracy is defined as the percentage of correctly predicted optical diagnoses of the CAD-CNN system and/or endoscopist compared to the gold standard pathology. For the calculation of the accuracy, adenomas and SSLs will be dichotomised as neoplastic polyps, while HPs and other non-neoplastic histology are considered non-neoplastic.

Secondary outcome

- The mean duration in seconds of the CAD-CNN system to make a per polyp diagnosis.
- The mean number of attempts of the CAD-CNN to make a diagnosis per polyp.
- The ratio of unsuccessful diagnoses from all diagnoses of the CAD-CNN system. An unsuccessful diagnosis/failure of the CAD-CNN system is defined as more than 3 unsuccessful attempts.
- The number of diminutive polyps per colonoscopy that is resected and discarded without histopathological analysis with the optical diagnosis strategy (the CAD-CNN system or endoscopist).
- The percentage of colonoscopies in which diminutive polyps are characterised based on optical diagnosis, removed and discarded without histopathological evaluation (i.e. proportion of polyps assessed with high confidence).
- The percentage of colonoscopies in which the surveillance interval is based on the optical diagnosis of the CAD-CNN system and the patient can be directly informed of the surveillance interval after colonoscopy.
- The percentage of colonoscopies in which diminutive hyperplastic polyps in the rectosigmoid are left in situ.
- The diagnostic tests for optical diagnosis: sensitivity, specificity, positive and negative predictive value (PPV and NPV), and area under the curve (AUC).
- The accuracy rates on a per polyp basis.

Accuracy on a polyp basis is defined as the percentage of correctly predicted optical diagnoses of the CAD-CNN system and/or endoscopist compared to the gold standard pathology. For the calculation of the accuracy on a polyp basis, adenomas, SSLs and HPs are considered different subtypes.

PIVI-criteria
- Agreement between recommended surveillance intervals, based on optical diagnosis of diminutive polyps with high confidence, compared to surveillance recommendations based on histology of all polyps.
- The NPV of neoplastic lesions in the rectosigmoid, based on optical diagnosis of diminutive polyps with high confidence, compared to histology.

All outcome measures for HDWLE instead of NBI endoscopy light.

Study description

Background summary

Rationale: Diminutive colorectal polyps (1-5mm in size) have a high prevalence and very low risk of harbouring cancer. Current practice is to send all these polyps for histopathological assessment by the pathologist. If an endoscopist would be able to correctly predict the histology of these diminutive polyps during colonoscopy, histopathological examination could be omitted and practise could become more time- and cost-effective. Studies have shown that prediction of histology by the endoscopist remains dependent on training and experience and varies greatly between endoscopists, even after systematic training. Computer aided diagnosis (CAD) based on convolutional neural networks (CNN) may facilitate endoscopists in diminutive polyp differentiation. Up to date, studies comparing the diagnostic performance of CAD-CNN to a group of endoscopists performing optical diagnosis during real-time colonoscopy are lacking.

Objective: To develop a CAD-CNN system that is able to differentiate diminutive polyps during colonoscopy with high accuracy and to compare the performance of this system to a group of endoscopist performing optical diagnosis, with the histopathology as the gold standard.

Study design: Multicentre, prospective, observational trial. Study population: Consecutive patients who undergo screening colonoscopy (phase 2)

Main study parameters/endpoints: The accuracy of optical diagnosis of diminutive colorectal polyps (1-5mm) by CAD-CNN system compared with the accuracy of the endoscopists. Histopathology is used as the gold standard.

Study objective

The intended main result of this project is the realization of a CAD-CNN system prototype that optically diagnosis colorectal polyps during a colonoscopy with great precision and fast processing time. We hypothesize that this CAD-CNN system will be more accurate than endoscopists for making an optical diagnosis of diminutive polyps.

Study design

None

Intervention

None

Contacts

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Eligibility criteria

Inclusion criteria

- Patients older than 18 years undergoing a screening colonoscopy.
- Signed informed consent

Exclusion criteria

- Boston bowel preparation score < 6
- Incomplete colonosopy
- Diagnosis of inflammatory bowel disease, Lynch syndrome or (serrated) polyposis syndrome.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-10-2018
Enrollment:	292
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	09-06-2020
Application type:	First submission

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
NTR-new	NL8700
Other	METC AMC : W18-422

Study results