Development and validation of a training module using the Pentax i-Scan optical enhancement technique to encourage the use of the WASP criteria with different imaging techniques

No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23188

Source
NTR

Brief title
VIEW study

Health condition

Colorectal polyps, diminutive polyps, colorectal adenomas, sessile serrated lesions, hyperplastic polyps

Sponsors and support

Primary sponsor: Radboudumc
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

The accuracy of optical diagnosis of diminutive colorectal polyps, based on the examination of 30 videofragments using Pentax i-Scan OE.

Secondary outcome

- High confidence predictions (>90% confident about the diagnosis)
- Interobserver agreement of polyp histology

Study description

Background summary

Rationale
To diminish the burden that comes with the current standard of care to remove and histopathologically evaluate all diminutive polyps encountered during colonoscopy, various classification schemes have been developed to optically predict polyp histology. One of these schemes is developed in 2015 by the Workgroup Serrated Polyps and Polyposis (WASP). Current research has focused on validating the WASP classification scheme for classification of colorectal diminutive polyps with the use of narrow band imaging (NBI). As a consequence, although previous results are promising it remains unclear whether these outcomes can be repeated when using different electronic chromoendoscopy (EC) techniques like the Pentax i-Scan optical enhancement (OE) system, currently used at the Radboudumc. The aim of this study is to develop and validate a training module for the WASP-criteria using images made with Pentax i-Scan OE.

Main objectives
To assess whether the pooled diagnostic accuracy of expert and trainee endoscopists increases after participating in a training module.

Study design
This study will be a multicenter interventional study comparing the diagnostic accuracy of diminutive colorectal polyps before and after a training module. Three training sessions will be organized in 2019 for gastroenterologists and gastroenterologists in training. To validate the training module the pooled diagnostic accuracy will be evaluated at three different moments (T0-T2): directly pre- and post-training, and three months post-training.

Study population
The study population will consist of gastroenterologists and gastroenterologists in training.

Main study parameters / endpoints

The main study parameter will be the concordance rate between optical diagnosis and histological diagnosis for diminutive polyps, in other words: the accuracy of optical diagnosis.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness
For this study no risks are expected. Participants will not benefit from this investigation. If applying the WASP criteria using Pentax i-Scan OE will prove to be safe, this may lead to a smaller number of polyps that need to be histopathologically assessed and as a consequence a smaller complication risk due to colonoscopic removal of diminutive polyps and reduced healthcare costs associated with histopathological evaluation.

Study objective

We expect an significant improvement in the pooled diagnostic accuracy of optical diagnosis of diminutive polyps by gastroenterologists (in training) after participating in a training session.

Study design

- January 2020: pre- and post-training tests (T0 and T1)
- April 2020: follow up-test (T2)

Intervention

Training session to educate gastroenterologists (in training) in applying the WASP criteria on colorectal diminutive polyps using Pentax i-Scan Optical Enhancement (OE).

Contacts

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Eligibility criteria

Inclusion criteria

- (Trainee) gastroenterologist
- Experience in endoscopically predicting polyp histology

Exclusion criteria

- Not able to participate in one of the training sessions

Study design

Design

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

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	28-01-2020
Enrollment:	16
Type:	Unknown

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	29-01-2020
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	NL8340
Other	CMO region Arnhem-Nijmegen : 2018-4514

Study results