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

Gepubliceerd: 29-01-2020 Laatst bijgewerkt: 18-08-2022

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.

Ethische beoordeling	Positief advies
Status	Anders
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23188

Bron
NTR

Verkorte titel
VIEW study

Aandoening

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

Ondersteuning

Primaire sponsor: Radboudumc
Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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0650000996

Wetenschappelijk

Radboudumc
Elsa Soons

0650000996

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Not able to participate in one of the training sessions

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Anders
(Verwachte) startdatum:	28-01-2020
Aantal proefpersonen:	16
Type:	Onbekend

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	29-01-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8340
Ander register	CMO region Arnhem-Nijmegen : 2018-4514

Resultaten