Discovery I study

Gepubliceerd: 21-07-2020 Laatst bijgewerkt: 13-12-2022

The PDR will increase with the use of the Discovery System.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21468

Bron
Nationaal Trial Register

Verkorte titel
Discovery I

Aandoening

Colorectal carcinoma, colorectal polyps, colorectal adenomas

Ondersteuning

Primaire sponsor: Radboudumc
Overige ondersteuning: Pentax Medical Europe

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Polyp detection rate (PDR)

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale
Adenoma detection rate (ADR) is known to be inversely correlated with the incidence of colorectal cancer (CRC). Multiple factors are considered to have a negative impact on the adenoma detection rate (ADR), one of them being human error. In recent years, a new solution to the human error in detecting adenomas has been developed; computer-aided detection (CADe) systems. Albeit performance of these systems on offline images and videos seems promising, evidence during real-time clinical practice is lacking. Recently, Pentax introduced a novel CADe-system, named “Discovery”.

Objective
The primary objective of this study is to evaluate the feasibility and safety of the Pentax CADe-system during colonoscopy procedures. We hypothesize that the use of this CADe-system is feasible safe and enables detection of colonic adenomas.

Study design
Prospective, multicenter cohort study including a total of 90 patients.

Study population
Patients aged ≥ 18 years, referred and scheduled for either diagnostic, screening (non-iFOBT based) or surveillance colonoscopy.

Main study parameter
The main study parameter is the polyp detection rate. Other study parameters will include the mean number of polyps, the polyp location, shape and size and the ADR.

Nature and extent of the burden and risks associated with participation, benefit and groups relatedness
Patients will be enrolled for a period of 30 days, starting at the day of the procedure and ending after 30 days of follow up. It is likely that the Pentax CADe system will lead to the detection of more (adenomatous) polyps and thereby resulting in more polypectomies, therefore participation in the study might lead to a longer procedure time and more adverse events, especially the risk of intraprocedural or delayed bleeding. Nonetheless, the risk of intraprocedural or delayed bleeding is estimated to be low, i.e. 1.8% and ≤0.1%, respectively. The removal of additional polyps that are detected by the CADe system might have a beneficial effect on the morbidity and mortality resulting from colorectal carcinoma, depending on the type of polyp that is removed during the procedure. The follow-up of the procedure (e.g. the number of hospital visits) will take place according to local guidelines.

Doel van het onderzoek

The PDR will increase with the use of the Discovery System.

Onderzoeksopzet

Findings during colonoscopy, SAE's up to 30 days post-colonoscopy

Onderzoeksproduct en/of interventie

Usage of Pentax Discovery Computer Aided Detection System.

Contactpersonen

Publiek

Radboudumc
Elsa Soons

0650000996

Wetenschappelijk

Radboudumc
Elsa Soons

0650000996

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- ≥ 18 years;
- Referred and scheduled for either diagnostic, screening (non-iFOBT based) or surveillance colonoscopy.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Known colorectal tumor or polyp on referral;
- Referral for a therapeutic procedure (i.e. endoscopic mucosal resection, intervention for lower gastro-intestinal bleeding, etc.);

- Inadequately corrected anticoagulation disorders or anticoagulation medication use;
- American Society of Anesthesiologists (ASA) score ≥ 3;
- Known or suspected inflammatory bowel disease;
- Inability to provide informed consent.
Patients that have inadequate bowel preparation, as measured by the Boston Bowel Preparation Score (BBPS): adequate bowel cleansing is considered when the total BBPS is ≥ 6 points along with a score ≥ 2 in each segment of the colon, will be included in the analysis. As the performance of the system in an inadequately prepared colon will also be an important outcome in this feasibility trial.

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:	Werving gestart
(Verwachte) startdatum:	01-09-2020
Aantal proefpersonen:	90
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	21-07-2020
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	NL8788
Ander register	CMO Arnhem-Nijmegen : 2020-6242

Resultaten