The European Polyp Surveillance study

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1. To investigate the optimal time interval for colonoscopy surveillance in patients with low-risk and high-risk adenomas (EPoS I trial and EPoS II trial); 2. To evaluate the yield of surveillance in patients with clinically relevant serrated polyps...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Benign neoplasms gastrointestinal
Study type	Interventional

Summary

ID

NL-OMON55632

Source
ToetsingOnline

Brief title
EPoS

Condition

- Benign neoplasms gastrointestinal
- Gastrointestinal neoplasms benign

Synonym
'adenoma', 'polyp'

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: er zijn nog geen subsidies verleend voor dit onderzoek. Het onderzoek zal worden opgestart en tegelijkertijd zullen er subsidie aanvragen worden ingediend. De vroegtijdige start is mogelijk doordat in Europees verband de nodige databases al zijn gecreëerd die ook beschikbaar zijn voor de Nederlandse tak van het onderzoek.

Intervention

Keyword: colonoscopy, colorectal cancer, prevention, surveillance interval

Outcome measures

Primary outcome

The primary endpoint for all three studies is the incidence of CRC and advanced adenomas (advanced neoplasia) at years 3, 5 and 10, where applicable.

Secondary outcome

The following endpoints will also be compared in the different arms in EPoS I and II, and presented in EPoS III:

• Colorectal cancer mortality

• Cost-effectiveness

• Yield of advanced adenomas, (non-advanced) adenomas and serrated polyps

• Adverse events

Study description

Background summary

Like in other European countries, a nationwide screening programme for colorectal cancer (CRC) was recently introduced in the Netherlands. This will result in an expansion of the population diagnosed with CRC precursor lesions (e.g. adenomas and serrated polyps). These individuals are in need for surveillance strategies to prevent future CRC incidence and mortality from CRC. However, there is a striking lack of clinical trials about the most optimal time interval for surveillance. In order to assure surveillance for those patients who are most likely to benefit as well as to minimize potential harms and burden, the determination of the proper surveillance interval to inform health care systems is of paramount importance. To identify proper surveillance intervals for individuals with adenomas as well as clinically relevant serrated polyps the European Polyp Surveillance (EPoS) working group was established.

Study objective

1. To investigate the optimal time interval for colonoscopy surveillance in patients with low-risk and high-risk adenomas (EPoS I trial and EPoS II trial);
2. To evaluate the yield of surveillance in patients with clinically relevant serrated polyps (EPoS III registry).

Study design

The EPoS project consists of two randomized controlled trials and an observational cohort study:
- EPoS I trial randomizes patients with low-risk adenomas into 5 or 10-year surveillance;
- EPoS II trial randomizes patients with high-risk adenomas into 3 or 5-yearly surveillance;
- EPoS III registry will evaluate the yield of surveillance colonoscopy at 5 and 10 years after baseline removal of serrated polyps.

Intervention

Randomisation between different surveillance intervals (see study design)

Study burden and risks

For every colonoscopy there is a risk for perforation and bleeding and an associated burden. In EPOS trials I and II participants will be randomized to less frequent or more frequent surveillance intervals. The most plausible outcome of these trials is a similar cumulative incidence of CRC between groups, with alternating burden of colonoscopic surveillance. The EPOS III trial will be a registry. No additional burden or risks are to be expected.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- men and women age 40-74 years;
- cecal intubation during baseline colonoscopy
- adequate colonic cleansing, with Boston Bowel Cleansing Score >=2 points in all colonic segments
- complete excision of all polyps at baseline colonoscopy findings
- randomization must be performed no longer than 26 weeks (182 days) from completion date of baseline colonoscopy.

Exclusion criteria

- lack of informed consent
- history of colorectal cancer or adenomas (prior to baseline colonoscopy)
- history of serrated polyps >= 10 mm in diameter at any colorectal location or >= 5 mm if located proximal to the splenic flexure
- more than 10 adenomas
- incomplete colonoscopy
- incomplete endoscopic excision of polyps
- genetic cancer syndrome (adenomatous or serrated polyposis syndrome; Lynch or Lynch-like syndrome)
- inflammatory bowel disease

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-12-2016
Enrollment:	4707
Type:	Actual

Ethics review

Approved WMO Date:	17-11-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-02-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-02-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-04-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-07-2016

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-03-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-03-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-04-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-09-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-10-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-02-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-06-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-08-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-10-2018

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-05-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-11-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
ClinicalTrials.gov	NCT02319928
CCMO	NL54615.018.15