

Standardizing TrAining for endoscopic Resection of Large Non-Pedunculated Colorectal Polyps: it is prime-time to change practice

No registrations found.

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

Summary

ID

NL-OMON24519

Source

Nationaal Trial Register

Brief title

STAR-LNPCP

Health condition

Colorectal cancer, Polyps, Adenomas, Optical diagnosis, EMR

Sponsors and support

Primary sponsor: Maastricht University Medical Center

Source(s) of monetary or material Support: KWF kankerbestrijding (project number 10089)

Intervention

Outcome measures

Primary outcome

Local recurrence rate after 6 months

Secondary outcome

Radical (R0) resection rate

Complication rate

Number of repeat colonoscopies

Referral rate to surgery

Patient satisfaction regarding clinical outcomes of endoscopic resection

Cost-effectiveness

Study description

Study objective

We hypothesize that standardized training for endoscopist comprising endoscopic diagnosis followed by a therapeutic plan and high-quality endoscopic resection performance will reduce the number of recurrence after resection of large non-pedunculated colorectal polyps. We also expect a reduced number of colonoscopies and surgeries needed to definitively remove these neoplasms.

Study design

1. Initial colonoscopy
2. Potential intervention colonoscopy
3. Surveillance colonoscopy after 6 months

Intervention

Training of endoscopists in optical diagnosis and endoscopic resection (EMR) of large, non-pedunculated colorectal polyps

Contacts

Public

Scientific

Eligibility criteria

Inclusion criteria

Patients, ≥ 18 years old, with large, non-pedunculated colorectal polyp(s) found during colonoscopy

For endoscopists/centers: experienced colonoscopists (500 colonoscopies without supervision), availability of HD materials

Exclusion criteria

For patients: unable to give informed consent

For endoscopists: not qualified for the nationwide screening program

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2019
Enrollment:	1400
Type:	Anticipated

Ethics review

Positive opinion	
Date:	12-09-2018
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	NL7255
NTR-old	NTR7477
Other	METC Maastricht University Medical Center : 2017-0017

Study results