A prospective study stratifying patients to follow up intervals based on risk of recurrence post wide field colonic EMR.

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To prospectively validate the SERT scoring system for adenoma recurrence rates around the EMR scar after WF-EMR with SCAR technique applied to the defect margin.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Benign neoplasms gastrointestinal
Study type	Observational non invasive

Summary

ID

NL-OMON44414

Source
ToetsingOnline

Brief title
PROSPER study

Condition

- Benign neoplasms gastrointestinal

Synonym
Large colorectal polyps

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Colon, EMR, Recurrence

Outcome measures

Primary outcome

The primary outcome measure is the presence of residual/recurrence of polyp tissue at or immediately surrounding the previous EMR site at follow up colonoscopic procedures (at 18 months and 36 months) after WF-EMR involving the SCAR technique of either SERT 0 lesions or SERT 1-4 lesions.

Secondary outcome

The secondary outcome measures are the following:

• Lesion characteristics and procedural characteristics of the initial EMR data of SERT 0 and SERT 1-4, such as

- Location of the lesion

- Rate of *en bloc resection* (removing entire lesion in one snare) with histologically confirmed clear margins

- The number of snare resections needed to achieve complete clearance

- Number of injections required for haemostasis

- Location of bleeding vessels

- Size/number of bleeding vessels

- Time required for EMR

- Frequency of adverse events, bleeding, perforation or readmission

- Need for surgery

- Evidence of malignancy

• The presence of residual/recurrence of polyp tissue at or immediately

surrounding the previous EMR site at follow up colonoscopic procedures at 6 months after WF-EMR involving the SCAR technique of SERT 1-4 lesions. .

• Histology and dysplasia of the residual/recurrence at or immediately surrounding the previous EMR site detected at all follow up colonoscopic procedures

• The frequency of malignant submucosal invasive disease present within the residual/recurrence of polyp tissue at or immediately surrounding the previous EMR site

• The frequency of the necessity to perform an additional surgical resection due the impossibility to endoscopically resect residual/recurrence of polyp tissue or due to malignant submucosal invasive disease at or immediately surrounding the previous EMR site

Study description

Background summary

Colonoscopy and polypectomy reduces the anticipated incidence of colorectal malignancy in patients with significant adenomatous polyps by approximately 80% in long term follow up. Removal of flat colonic neoplasia 20mm in size or larger is more complex and requires specific endoscopic techniques, one such technique being termed wide field endoscopic mucosal resection (WF-EMR). This procedure has been shown to be safe and effective at resecting lesions limited to the mucosa, especially in combination with thermal treatment (Snare Tip Soft Coagulation) of the EMR defect margin. This technique is also known as the SCAR technique.
An important longer-term complication of EMR of large flat colonic neoplasia is the phenomenon of residual polyp tissue or polyp recurrence, which is detected by surveillance colonoscopies (SC). SC are performed at defined intervals after the index procedure. Increasing evidence suggests that identifiable factors at the initial EMR could predict recurrence at SC1[6]. Therefore a risk score for recurrence after EMR known as the Sydney EMR Recurrence Tool (SERT) is

developed, which will be validated in this prospective cohort study.

Study objective

To prospectively validate the SERT scoring system for adenoma recurrence rates around the EMR scar after WF-EMR with SCAR technique applied to the defect margin.

Study design

Prospective multicenter cohort study to investigate the safety of triaging the timing of follow up after colonic EMR based on the Sydney EMR Recurrence Tool.

Study burden and risks

Harm to the patient: SERT 1-4 patients are essentially receiving current standard treatment and so no harm is expected. SERT 0 patients are undergoing first surveillance colonoscopy at 18 months rather than 4-6 months. Therefore there is a risk that a small remnant of adenomatous tissue grows during this time, and that might causes harm to the patient before it is detected at the 18 months surveillance procedure. We expect only a very small risk that recurrence has progressed to such an extent in 18 months that it is not endoscopically treatable and requires surgery or that it might have developed into cancer.

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

Patients referred for endoscopic removal of a large sessile colonic polyp sized bigger or are 20mm
Age >18 years
Able to give informed consent to involvement in trial

Exclusion criteria

-Lesion involving the ileocaecal valve
-Pregnancy: currently pregnant or attempting to become pregnant
-Lactation: currently breastfeeding
-Taken clopidogrel within 7 days
-Taken warfarin within 5 days
-Had full therapeutic dose unfractionated heparin within 6 hours
-Had full therapeutic dose low molecular weight heparin (LMWH) within 12 hours
-Known clotting disorder
-Previous attempt at EMR of the polyp referred for resection
-Known with or the endoscopic suspicion of the presence of hereditary polyposis, such as FAP, Lynch syndrome and serrated polyposis syndrome or bowel cancer syndrome

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	250
Type:	Anticipated

Ethics review

Approved WMO Date:	13-10-2017
Application type:	First submission
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	NCT02957058
CCMO	NL61758.018.17