Clip Placement Following Colonic Endoscopic Mucosal Resection (EMR). The CLIPPER Study: A nationwide multicentre randomized clinical trial.

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To investigate whether prophylactic clipping (PC) after endoscopic mucosal resection (EMR) of a flat polyp in the colon prevents delayed bleeding (DB) and is cost-effective.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Interventional

Summary

ID

NL-OMON52818

Source
ToetsingOnline

Brief title
CLIPPER

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
EMR, polypectomy, polyp-removal

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: MLDS

Intervention

Keyword: delayed bleeding, Endoclip, Endoscopic Mucosal Resection (EMR), large polyp

Outcome measures

Primary outcome

The primary endpoint measure is: (incidence of) significant DB <30days.

DB is defined as any bleeding occurring after the completion of the procedure necessitating blood transfusion, hospitalization, or re-intervention (either repeat endoscopy, angiography, or surgery) [15,20]. Self-limiting bleeding managed on an outpatient basis or only emergency room presentation without further hospitalization / blood transfusion is not included.

Secondary outcome

Secundary study parameters are amongst others: costeffectivity, quality of life, (severe) complications related to PC, non-radical polypresection.
possibly confounding risk factors for the development of DB (eg. age, BMI, smoking behaviour etc.).

Study description

Background summary

Approximately 17,500 endomucosal resections (EMR) of flat polyps are yearly performed in the colon, mostly due to the spin-off of the national colorectal cancer-screening program (NCCS). The most prevalent complication is delayed bleeding (DB) with an incidence of 3%-10%. DB leads to hospitalization and additional colonoscopies with substantial economic impact. A strategy to prevent DB was investigated in several studies comparing prophylactic clipping (PC) with a conservative (non-PC) management. Indeed, a positive effect on the incidence of DB was reported in the PC group in these studies. Limitations of

these studies include the retrospective design, inclusion of all types of polyps and sizes, lack of power and all reported studies were only performed in tertiary referral hospitals. The current study proposal aims to investigate the role of PC in preventing DB and the cost-effectiveness of this intervention in clinical practice.

Study objective

To investigate whether prophylactic clipping (PC) after endoscopic mucosal resection (EMR) of a flat polyp in the colon prevents delayed bleeding (DB) and is cost-effective.

Study design

We will perform a multi-center, randomized, patient- blinded multicenter trial, comparing two treatment strategies in 314 patients undergoing EMR for a colonic lesion >2
cm.

Intervention

PC will be compared to standard care (no PC). Clips will be placed to approximate the resection plane with a density of at least 1 clip per cm.

Study burden and risks

The patients are burdened with questionnaires (20min) at baseline and 30 days, 3 months and 180 days after the procedure .

178 patient will undergo PC. No complications of PC are known.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- laterally spreading or sessile polyp morphology proximal to the splenic flexure, measuring 2-6cm
- Method of polyp removal is EMR
- patients >18 years old
- Written informed consent

Exclusion criteria

- Pregnancy
- Active inflammatory colonic conditions (e.g. inflammatory bowel disease)
- American Society of Anesthesiology (ASA) Grade IV-V
- Previous resection or attempted resection of a lesion less than 30 days ago
- Residual adenoma left after previous intervention
- >1 lesion removed in the same session
- Involvement of valvula Bauhini or orificium appendix
- Endoscopic appearance of invasive malignancy (non-lifting Kato D, Kudo V pit pattern)
- Macroscopic non-radical resection
- Clip deployed prior to the completion of the EMR for a perforation or a major intra-procedural bleeding not treatable by coagulation

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-05-2018
Enrollment:	356
Type:	Actual

Medical products/devices used

Generic name:	endoclips
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	23-01-2018
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	06-03-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	16-04-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	08-05-2018
Application type:	Amendment

Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	23-08-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	06-02-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	08-05-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	10-08-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NCT03309683
CCMO	NL62949.091.17

Study results

Date completed:	01-08-2022
Actual enrolment:	356