

Limited surgival resection of colon polyps

No registrations found.

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

Summary

ID

NL-OMON23123

Source

Nationaal Trial Register

Brief title

LIMERIC

Health condition

colon polyps, irradical endoscopic resection, endoscopic assisted wedge resection

Sponsors and support

Primary sponsor: UMC Utrecht

Source(s) of monetary or material Support: fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

safety of limited endoscopic assited laparoscopic wedge resection(EAWR)

Secondary outcome

- effectiveness of EAWR, defined as the number of radical resection (margin of normal colonic mucosa of at least 1mm)

- morbidity of limited EAWR 3 months after the procedure
- recurrence rate at 6 months
- total procedure related costs of limited EAWR
- implementation of limited EAWR in the Netherlands

Study description

Background summary

The detection rate of colon polyps difficult to resect endoscopically is rising. Available techniques such as EMR/ESD are not applicable to all cases. Segmental colectomy is associated with significant morbidity and mortality.

Therefore, we introduced a limited endoscopy assisted laparoscopic wedge resections (EAWR) by using a linear stapler without anastomosis for the treatment of such polyps.

The objective is to study the safety and radicality of limited EAWR for the treatment of difficult colon polyps. Therefore, our primary endpoint is the 30-day morbidity after an EAWR. One of the secondary endpoints are the costs related with the procedure.

Study objective

A limited endoscopic assisted laparoscopic wedge resection of colon polyps is safe and effective.

Study design

- 30-day morbidity
- 6 months recurrence of adenomatous tissue by colonoscopy

Intervention

laparoscopic wedge resection and a colonoscopy during this intervention

Contacts

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Eligibility criteria

Inclusion criteria

- A difficult non-invasive polyp that cannot be removed by standard EMR/ESD technique as assessed by an experienced gastroenterology expert panel
- A non-lifting recurrence of adenomatous tissue after irradical endoscopic removal.
- Resection of the scar after a prior endoscopic removal of an invasive T1 CRC without free resection margins but without high risk features of lymph node metastasis
- age of 18 years of older

Exclusion criteria

- Pregnancy
- > 50% circumferential growth of the polyp in the lumen

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-01-2017
Enrollment:	115
Type:	Anticipated

Ethics review

Positive opinion	
Date:	24-01-2017
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	NL6200
NTR-old	NTR6364
Other	UMX Utrecht METC Approvel number : Reference 16-571

Study results