Multicenter, randomised controlled trial comparing endoscopic Mucosal resection (EMR) And endoscopic submucosal dissecTIon (ESD) for resection of Large Distal non-pedunculated colorectal Adenomas

Published: 22-12-2015
Last updated: 19-04-2024

The aim of this study is to perform a randomized comparison between ESD and EMR in large (>20 mm) distal non-pedunculated polyps in a Western population. We aim to compare both procedures with regard to recurrence rates and radical (R0) resection...

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

Summary

ID

NL-OMON47389

Source
ToetsingOnline

Brief title
MATILDA-study

Condition

- Benign neoplasms gastrointestinal

Synonym
adenoma polyp

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W,KWF Kankerbestrijding;subsidie datamanagement

Intervention

Keyword: adenomas, colorectal, EMR, ESD

Outcome measures

Primary outcome

- to compare the recurrence rate at follow-up colonoscopy after 6 months, observed from resected residual disease or, if not present, from biopsies of the scar

Secondary outcome

- to compare the radical (R0-)resection rate, defined as dysplasia free vertical and lateral resection margins at histology

- To compare the cost effectiveness at 36 months

- To compare the perceived burden and quality of life among patients

- To compare the surgical referral rate defined as the number of patients that are referred for surgical management at 36 months

- To compare the complication rate

- To compare the long-term recurrence rate at follow-up colonoscopy after 36 months, observed from resected residual disease or, if not present, from biopsies of the scar

Study description

Background summary

Endoscopic resection of polyps in the colon is a cornerstone of effective CRC prevention, because it allows the removal of precursor lesions that may progress to cancer. Two modalities are available for the endoscopic resection of lateral spreading polyps (LSTs), including endoscopic mucosal resection (EMR) and endoscopic submucosal dissection (ESD). EMR is quick, easy to perform and associated with a low number of complications. However, polyps larger than 2 cm often cannot be removed in one piece (en-bloc) and are removed in pieces (piecemeal (p)EMR), resulting in high recurrence rates. For this reason ESD was developed, which enables high en-bloc resection rates even in large polyps, and is associated with low recurrence rates. As a disadvantage, ESD is much more difficult to perform and associated with higher complication rates and a longer procedure time. Currently, a direct randomized comparison between ESD and EMR (with APC or tipping in adjunct to pEMR) is lacking and therefore current guidelines are not able to guide practice on this topic.

Study objective

The aim of this study is to perform a randomized comparison between ESD and EMR in large (>20 mm) distal non-pedunculated polyps in a Western population. We aim to compare both procedures with regard to recurrence rates and radical (R0) resection rate, and to put this into perspective against the costs and complication rates of both strategies and the burden perceived by patients on long term-term (36 months).

Study design

Multicenter randomized controlled trial.
Due to the nature of the treatment, neither patients nor endoscopists participating in this study will be blinded.

Intervention

In the EMR-arm, endoscopic resection will be performed using the EMR technique (with APC or tipping in adjunct to pEMR), whereas patients randomized to the ESD-arm will undergo resection using the ESD technique.

Study burden and risks

The two endoscopic resection techniques investigated in this study are standard care in the Netherlands. A follow-up colonoscopy is performed 6 and 36 months after the procedure, which is standard care in the Netherlands. In case of

macroscopic residual disease this will be resected, which is standard care. If not, biopsies of the scar and surrounding area will be taken, which is optional and recommended in standard care and fixed care in this study. With regard to the quality of life questionaires, we aimed to minimize questionnaire length and density of sampling to the highest necessary in order to balance the effort required by the patient to answer the questionnaires with the estimated goal of quality of life analysis for this study. Taken this together, neither an unacceptable risk nor a direct benefit is expected for patients participating in this study.
This study will increase the knowledge on the preferred endoscopic method in Western countries that is currently unknown. This is important, as the detection rate of large distal non-pedunculated adenomas is expect to further increase with the introduction of the Dutch CRC screening program. The study will therefore support an optimal use of health resources in the future.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- non-pedunculated polyp larger than 20 mm in the rectum, sigmoid or descending colon found during colonoscopy
- indication for endoscopic treatment
- >=18 years old
- written informed consent

Exclusion criteria

suspicion of malignancy, as determined by endoscopic findings (invasive Kudo pit pattern, Hiroshima type C) or proven malignancy at histology
- prior endoscopic resection attempt
- presence of synchronous distal advanced carcinoma that requires surgical resection
- the risk exceeds the benefit of endoscopic treatment, such as patient*s with an extremely poor general condition or a very short life expectancy
- the inability to provide informed consent

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-04-2016
Enrollment:	254
Type:	Actual

Ethics review

Approved WMO Date:	22-12-2015
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	23-02-2016
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	23-03-2016
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	25-05-2016
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	10-08-2016
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	26-04-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	01-11-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	15-08-2018
Application type:	Amendment
Review commission:	METC NedMec

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
CCMO	NL53734.041.15