Pilot study LumenR assisted ESD in rectal adenomas in the Netherlands

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This study aims to assess the efficacy, safety and effectiveness of LumenR-assisted ESD for the treatment of large rectal adenomas. In addition, the learning curve for this technique in endoscopists with experience in standard ESD is assessed.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Benign neoplasms gastrointestinal
Study type	Interventional

Summary

ID

NL-OMON43376

Source
ToetsingOnline

Brief title
Rectal LumenR assisted ESD

Condition

- Benign neoplasms gastrointestinal

Synonym
Rectum adenoma, Rectum polyp

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Antonius onderzoeksfonds

Intervention

Keyword: Colonoscopy, ESD, Rectal adenoma

Outcome measures

Primary outcome

Our main study parameter is the number of en bloc resections and the en bloc resection rate after LumenR assisted ESD.

Secondary outcome

The following secondary parameters are designed to further study the efficacy and safety of LumenR assisted ESD:

- Procedural time
- Number of patients with a histological R0-resection
- Adenoma recurrence rate at 6 months after the procedure
- Number of procedures with cessation of the ESD procedure due to technical difficulties
- Number of intra procedural complications (bleeding or perforation) for which an additional intervention, defined as transfusion, admission, radiologic intervention or surgical treatment is required.
- Number of patients with early (48 hours) and late (until 14 days) post procedural complications for which additional treatment is necessary, defined as presentation at the emergency ward, transfusion, admission, repeat endoscopy, radiologic intervention or surgical treatment

Study description

Background summary

Endoscopic submucosal dissection (ESD) and endoscopic mucosal resection (EMR) are both considered to be effective treatment strategies for large rectal adenomas. ESD has the advantage of achieving en bloc resection with a lower local recurrence rate compared to piecemeal endoscopic mucosal resection. Furthermore, ESD reportedly has higher complications rates, prolonged procedural times and endoscopists need to have profound training before they can safely perform this procedure. Therefore a new endoscopic ESD overtube (LumenR) is developed to overcome the technical difficulties associated with ESD.

Study objective

This study aims to assess the efficacy, safety and effectiveness of LumenR-assisted ESD for the treatment of large rectal adenomas. In addition, the learning curve for this technique in endoscopists with experience in standard ESD is assessed.

Study design

A multicentre pilot cohort study to investigate the efficacy and safety of LumenR assisted ESD in patients with large rectal adenomas performed by endoscopists with sufficient ESD experience.

Intervention

Eligible patients will receive LumenR-assisted ESD performed by an endoscopist with sufficient ESD experience.

Study burden and risks

The patients will receive a colonoscopy with LumenR assisted ESD for the endoscopic remorval of a known large rectal polyp. This device is not associated with additional risks, but ESD itself is associated with a relatively high procedure related bleeding and perforation rate. A benefit for the patient is that he or she will receive endoscopic treatment of a large rectal polyp which was historically removed with a surgical treatment. When this adenoma polyp can be removed in an endoscopic fashion surgery can be avoided and therefore its associated morbidity and mortality as well.

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

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- The patient is diagnosed during a complete colonoscopy with a large non-pedunculated rectal adenoma (sessile or laterally spreading) with:
• Diameter of >= 20mm and <= 50mm (estimated at the discretion of the endoscopist or by an opened biopsy forceps/resection snare)
• Circumferential involvement of the rectal wall of <= 50 %
• The lower borders and upper borders of the adenoma are located between 1 cm and 15 cm from the dentate line
- If biopsies are taken at the primary diagnostic procedure, these are allowed to show benign intraepithelial (low or high grade) dysplasia. Biopsies are not a prerequisite for inclusion.
- ASA classification I-III

- Is aged of 18 years or older
- Signed the informed consent form

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Endoscopic suspicion for submucosal invasive cancer, with for example one of the following characteristics:
• Kudo pit pattern type V
• Excavated/depressed type morphology (Paris type 0-IIc or 0-III)
• Fold convergence
• Large smooth nodule > 1 cm in a flat lesion
- Histopathology or biopsy proven invasive or malignant disease
- The targeted lesion consists of residual polypoïd tissue after previous (endoscopic) treatment of this lesion
- The patient is known with active inflammatory bowel disease (morbus Crohn or ulcerative colitis) of the colorectum.
- Patients with suspicion of polyposis syndrome
- Patients with a known irreversible coagulopathy, or patients with anticoagulational therapy (with warfarins, heparins, NOACS or double anti-platelet agents) for an indication wherefore temporarily cessation of the treatment is not possible.
- Patients with active bleeding from any source
- HIV-positive or immunocompromised patients
- Patients who receive chemotherapy
- Pregnant patient

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	25

Type:	Anticipated

Medical products/devices used

Generic name:	LumenR Cannula Retractor(TM)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	02-05-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-07-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-08-2016
Application type:	Amendment
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
CCMO	NL56236.018.16