Resection of mucosa of human colon or rectal tissue using a new endoscopic device, the SuMO (Sub Mucosal Operation) Tissue Access and Resection System

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The SuMO System showed good results for mucosal resection in a porcine model. This study is developed to evaluate the feasibility and safety of the SuMO (submucosal operation) Access and Tissue Resection System in human colon and rectum tissue.

Ethical review	Approved WMO
Status	Pending
Health condition type	Benign neoplasms gastrointestinal
Study type	Interventional

Summary

ID

NL-OMON34055

Source
ToetsingOnline

Brief title
Endoscopic mucosal resection in the colon and rectum using SuMO

Condition

- Benign neoplasms gastrointestinal

Synonym
polyp

Research involving
Human

Sponsors and support

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

Intervention

Keyword: mucosa, resection, SuMO

Outcome measures

Primary outcome

Feasibility and safety of mucosal resection of colonic or rectal tissue using

the SuMO Access and Tissue Resection System. Adverse events, serious adverse

events, unexpected adverse events.

Secondary outcome

Group A:

* bloodloss

* en bloc resection

Group B:

* En bloc resection

* Macroscopic radical resection

Study description

Background summary

Endoscopic mucosal resection (EMR) is used for the treatment of benign or (pre)neoplastic mucosal lesions of the digestive tract. EMR is used when it is not possible to perform a polypectomy. Larger lesions, more than 2 cm are often not possible to treat with EMR. Patients than have to be treated surgicaly. The

SuMO (submucosal operation) Access and Tissue Resection System is developed to treat these lesions. For these patients major surgical resections and operations could be avoided with additionaly less morbidity.

Study objective

The SuMO System showed good results for mucosal resection in a porcine model. This study is developed to evaluate the feasibility and safety of the SuMO (submucosal operation) Access and Tissue Resection System in human colon and rectum tissue.

Study design

Prospective cohort study

Intervention

Mucosal resection using the SuMO system in healthy colonic tissue in group A. Mucosal resection of benign mucosal lesion in colon or rectal tissue using the SuMO.

Study burden and risks

Patient burden in group A will be an extra 30 minutes that are added to the total procedure time. For group B no extra burden other than the burden associated with EMR. Possible risks for both groups are risks that are associated with standard surgical or endoscopic care. For endoscopy this will be the risk of perforation, bleeding and infection. Additionaly, risks of anasthetics.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
1105 AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* The patient is between 18 and 80 years of age.
* The patient is willing to be available for the appropriate follow-up for the duration of the study
* Written informed consent;Group A:
* Indication for a partial colon resection via laparoscopy or laparotomy for a benign or malignant lesion.
Group B:
* Indication for an endoscopic mucosal resection (EMR) for a benign rectal lesion.
* Diameter of lesion < 4cm

Exclusion criteria

* The patient is not between 18 and 80 years of age.
* The patient is unwilling to be available for the appropriate follow-up for the duration of the study.
* The patient is mentally incompetent and does not understand the procedure and associated risks.
* The patient is unable and/or unwilling to cooperate with study procedures or required follow-up visits.
* The patient has any of the following conditions:
o Recent myocardial infarction (acute MI)
o Bleeding disorders/anticoagulation (non-reversible bleeding disorders or coagulopathy)
o Prior colorectal surgery
o Pregnant or actively breastfeeding.
o Any other condition or anatomical limitation that would contraindicate them for laparoscopic surgery, a lower GI endoscopic procedure, or surgical anesthesia.;Group A:
* ASA class IV or V

* Patient is suffering from any of the following conditions:
o Crohn*s Disease;Group B:
* ASA class IV or V
* Patient is suffering from any of the following conditions:
o Crohn*s Disease
o Severe diverticulitis
o Previous rectal ESD or EMR

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2011
Enrollment:	20
Type:	Anticipated

Medical products/devices used

Generic name:	SuMO (sub mucosa operation) Tissue Access and Resection System
Registration:	No

Ethics review

Approved WMO

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
CCMO	NL34626.018.10