The volume of colorectal surgery for benign polyps in the past decade

No registrations found.

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27938

Source
Nationaal Trial Register

Health condition

Surgery
Colonoscopy
Colorectal adenoma
Colorectal polyp

Chirurgie
Coloscopie
Colorectaal adenoom
Colorectale poliep

Sponsors and support

Primary sponsor: Academic Medical Center
Source(s) of monetary or material Support: Investigator initiated, no formal funding by third or commercial parties

Intervention

Outcome measures

Primary outcome

Our main study endpoint is the overall volume of colorectal surgery as the treatment for benign colorectal polyps and volume changes in the past decade.

Secondary outcome

The following secondary study parameters are designed to further study the polyp, surgical and pre surgical endoscopy characteristics.

- Indications for surgical resection

- Reason for referral for surgical resections

- Types of surgery performed

- Complication and mortality rate associated with benign colorectal surgery

- Polyp location

- Mean polyp size

- Polyp morphology

- Endoscopic diagnosis during endoscopy

- Histopathologic diagnosis after surgery in the resection preparation

- Diagnosis made by gastroenterologist, surgeon or internist for referral for surgery.

- Indication for the colonoscopy that identified the large colorectal lesion

- Number of colonoscopies performed before referral for surgical resection

- Number of endoscopic polypectomy procedures

- Number of endoscopic polypectomy attempts after referral to a tertiary center

- Complication rate and mortality associated with colonoscopy

Study description

Background summary

Traditionally large and complex non-pedunculated colorectal polyps have been managed with surgical resection (SR). However over the past decade endoscopic resection (ER) techniques,

such as piecemeal endoscopic mucosal resection (pEMR) and endoscopic submucosal dissection (ESD) of these polyps, have progressed significantly and are now applied in many endoscopy centers around the world. Replacing surgery by ER of these complex colorectal polyps will reduce surgerical morbidity, mortality and costs. It remains unclear to what extent ER has replaced SR. We therefore aim to perform a multicenter retrospective cohort study in the province of Noord-Holland in the Netherlands to assess the total volume of colorectal surgery for benign colorectal polyps and the absolute and relative volume changes over the past decade. Secondly, we will assess endoscopic characteristics of the resected lesions, surgery characteristics as well surgical related morbidity and mortality. This study was proposed to all 15 regional and 2 academic hospitals in the province of Noord-Holland (1.7 million inhabitants) in the Netherlands. We aim to include all patients who underwent surgical bowel resection for benign colorectal polyps between 2005 and 2015. Patients will be retrieved from the prospective nationwide Dutch Pathology Registry (PALGA-database), which was searched for all histopathological reports of surgical resection specimens containing benign colorectal polyps. Data concerning polyp, endoscopic and surgical characteristics will be collected from the patient records.

Study objective

This study aims to describe the volume of patients referred for colorectal surgery for removal of benign colorectal polyps and its morbidity and mortality in the North-West of the Netherlands between 2005 and 2015.

Study design

01-01-2016: submission of a conference abstract to the Digestive Disease Week 2017 and the Digestive Disease Days 2017

Intervention

There are no formal interventions, since this is a retrospective multicenter cohort study in order to investigate the volume of performed colorectal surgery for benign colorectal polyps in the past decade.

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Eligibility criteria

Inclusion criteria

We will retrospectively include all patients who were treated with surgical resection of their benign large colorectal lesion in the regional hospitals and academic centers in the province of North-Holland.

In order to be eligible to be included in this study a patient must meet all of the following criteria:
- The patient underwent colorectal surgery between 2005 and 2015 in one of the participating hospitals for at least onea:
- Colorectal polyp with benign histopathology, defined as a tubular, tubulovillous or villous adenoma or sessile serrated adenoma/polyp with low grade or high grade dysplasia, sessile serrated lesions or traditional serrated lesions with or without (high or low grade) dysplasia and hyperplastic polyps.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from inclusion in this study:

- Clear signs of submucosal invasion at histopathology of the resection preparation

- Known with Inflammatory Bowel Disease

- Known with polyposis syndromes, like Familial Adenomatous Polyposis, Lynch Syndrome and Serrated Polyposis Syndrome

- Surgery for synchronous colorectal malignancy

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:	Recruitment stopped
Start date (anticipated):	01-01-2016
Enrollment:	0
Type:	Actual

Ethics review

Not applicable

Application type:	Not applicable

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	NL5870
NTR-old	NTR6294
Other	METC AMC : W15_289#15.0339

Study results