

Complex colorectal polyps

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| Submission date 12/07/2016 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 24/07/2016 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 10/05/2019 | Condition category Cancer | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims

Large polyps (growth of tissue with a stalk) in the colon or rectum which develop into bowel cancer if left untreated are increasingly identified at colonoscopy (a test where a small tube fitted with a camera and a light is fed through the length of the the colon to take a look) and because of bowel cancer screening. These large polyps can be removed at colonoscopy by snare resection and other techniques. Making sure that the polyp isn't cancerous already and choosing the best technique to remove it (best resection technique) are important and complications may occur. This study is reporting on the tailored endoscopic techniques required to treat these polyps and the outcomes after their removal, including rates of cancer (how many patients go on to develop cancer), need for salvage surgery (for example, to repair severe damage), polyp recurrence rates (number of polyps that come back) and complication rates.

Who can participate?

Adults aged 18 or over who have a large colorectal polyp to be removed with the aid of colonoscopy at St Mark's Hospital London.

What does the study involve?

Patients are admitted to hospital and undergo treatment to remove their their polyp at St Marks after discussion of their treatment options and providing informed consent as part of standard clinical practice. Anonymised patient data (data that has all identifying information for each patient removed) is kept in a secure database and analysed at the end of the study period with a view to publication and dissemination (sharing) of these data in the medical literature.

What are the possible benefits and risks of participating?

There will be no immediate direct benefit to those taking part. A registry will be created based on the findings of the study aiming to be beneficial to future patients who undergo polyp removal surgery. There are no significant risks of participating in this study.

Where is the study run from?

Wolfson Endoscopy Unit at St Mark's Hospital (London)

When is the study starting and how long is it expected to run for?

January 2010 to August 2015

Who is funding the study?
St Mark's Hospital and Academic Institute (London)

Who is the main contact?
Dr Zacharias Tsiamoulos

Contact information

Type(s)
Scientific

Contact name
Dr Zacharias Tsiamoulos

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Clinical audit number SUR/NP/15/038

Study information

Scientific Title
Complex colorectal polyps; tailoring endoscopic techniques and monitoring endoscopic outcomes

Acronym
CCP

Study objectives
Patients with large non-pedunculated colorectal polyps (NPCPs) are increasingly referred for piecemeal endoscopic mucosal resection (p-EMR). This prospective audit reports on the management of all patients with large NPCPs referred to a tertiary centre over a two and half

year period. We also aimed to describe features that contribute to complexity of large NPCPs, suitability for endoscopic resection in a tertiary centre and the endoscopic resection techniques required.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Clinical audit as part of good clinical practice

Study design

Observational case series

Primary study design

Observational

Secondary study design

Case series

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Piecemeal Resection Polypectomy techniques within St Mark's Hospital/Academic Institute, London North West Healthcare

Interventions

A prospective audit of consecutive patients with NPCPs $\geq 20\text{mm}$ referred for consideration of endoscopic resection to our tertiary centre between January 2010 and August 2012 was performed including the long term follow up until August 2015. Clinical and demographic information were recorded. NPCPs were evaluated in a standardised fashion at colonoscopy. After endoscopic evaluation, a resection strategy plan was formulated for each polyp where p-EMR was deemed suitable. Four variations of endoscopic resection technique were employed. Intraprocedural and immediate post-procedural adverse events (bleeding, perforation, vasovagal episodes and post-polypectomy syndrome) were recorded. Patients were followed up at 14 days post procedure with a telephone call to record any other complications. Post-operative admissions for complications were recorded. Patients underwent surveillance colonoscopies at between 3-9 months (early follow up) and then at 15 +/- 24 months (late follow up) for evaluation of polyp recurrence.

Intervention Type

Procedure/Surgery

Primary outcome measure

1. Total number of patients (referring letters / nature of referrals - local or tertiary) referred to Wolfson Unit for Endoscopy/Academic Institute
2. Piecemeal resection Outcomes (short term/15 day telephone, 3-6-9 months follow up-recurrence and long term/15-24-36 months follow up-recurrence)
3. Piecemeal resection complication rates (short and long term)
4. Patients referred to surgery (due to benign or malignant recurrence)

Secondary outcome measures

1. Management resection plan for all referrals (excised polyps and non-excised polyps /abandoned or not attempted cases)
2. Safety and Efficacy of the Piecemeal Resection techniques utilised
3. Safety of the patients (mortality and morbidity rates)

Overall study start date

01/01/2010

Completion date

01/08/2015

Eligibility

Key inclusion criteria

All consecutive referrals (local/tertiary referrals) to Wolfson unit for Endoscopy at St Mark's Hospital/Academic Institute at London North West Healthcare

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

>300

Total final enrolment

330

Key exclusion criteria

Bowel cancer screening patients

Date of first enrolment

01/01/2010

Date of final enrolment

01/08/2015

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Wolfson Unit for Endoscopy, St Mark's Hospital/Academic institute

Watford Road

Harrow

United Kingdom

HA1 3UJ

Sponsor information**Organisation**

London North West Healthcare NHS Trust

Sponsor details

Watford Road

Clinical Governance Department

Harrow

England

United Kingdom

HA1 3UJ

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/04cntmc13>

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

St Mark's Hospital and Academic Institute

Results and Publications

Publication and dissemination plan

Submission in progress

Intention to publish date

30/07/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | results | 01/08/2018 | | Yes | No |