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Complex colorectal polyps

Submission date 12/07/2016	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 24/07/2016	**Overall study status** Completed	
Last Edited 10/05/2019	**Condition category** Cancer	

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 though 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
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Additional identifiers

Protocol serial number
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

Primary study design
Observational

Study design
Observational case series

Study type(s)
Treatment

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 ≥ 20mm 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(s)
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)

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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

Study participating centre
Wolfson Unit for Endoscopy, St Mark's Hospital/Academic institute
Watford Road
Harrow
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Sponsor information

Organisation
London North West Healthcare NHS Trust

ROR
https://ror.org/04cntmc13

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
St Mark's Hospital and Academic Institute

Results and Publications

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