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Colorectal endoscopic mucosal resection (a procedure to remove precancerous, early-stage cancer or other abnormal tissues from the digestive tract) and reducing delayed bleeding in high risk patients

Submission date 03/12/2021	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 19/01/2023	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 11/01/2024	**Condition category** Digestive System	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol

Background and study aims

Delayed bleeding (bleeding from the bowel occurring more than 24 hours following endoscopic removal of polyps) is the most common complication following Endoscopic Mucosal Resection (EMR), occurring in up to 12% of cases depending on various risk factors. To date, there are no established guidelines to lessen this risk, with various studies of different treatment options showing some inconsistent and sometimes conflicting results. PuraStat® is a licenced product that can be applied through the endoscope directly following polyp removal to form a gel coat over the area where the polyp was removed. This product is already in use in UK hospitals in endoscopy procedures and has been proven to be completely safe.

The aim of the study is to collect data to help us understand whether applying PuraStat® after a colorectal polyp is removed can reduce the risk of delayed bleeding for a period of 30 days following EMR, compared to not using PuraStat® (standard practice).

Who can participate?

Patients undergoing EMR of colorectal polyps, and with high risk of delayed bleeding.

What does the study involve?

Patients with high delayed bleeding risk referred for EMR of colorectal polyps of 20mm or more in size will be randomised to receive either prophylactic application of PuraStat® to the EMR base (treatment group) or standard treatment (no PuraStat®, control group).

What are the possible benefits and risks of participating?

Whilst no financial reward can be made for taking part in the study, the information collected will be valuable to inform future practice.

There are no additional risks to taking part in the study as the risks of the procedure are not altered in the study.

Where is the study run from?
The study is Sponsored by Portsmouth Hospitals University NHS Trust (UK)

When is the study starting and how long is it expected to run for?
September 2021 to December 2024

Who is funding the study?
3-D Matrix UK Ltd.

Who is the main contact?
Prof Pradeep Bhandari (Chief Investigator), pradeep.bhandari@porthosp.nhs.uk

Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
281764

Protocol serial number
CPMS 50081, IRAS 281764

Study information

Scientific Title
Colorectal endoscopic mucosal resection and delayed bleeding: a prospective multicentre randomized controlled superiority trial comparing PuraStat® with conventional practice to reduce the risk of delayed bleeding after colorectal endoscopic mucosal resection in high-risk patients

Acronym

COLOSTAT

Study objectives
Use of a haemostatic gel (Purastat®) can reduce the risk of delayed bleeding after colorectal EMR in high-risk patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 13/09/2021, London - Bloomsbury Research Ethics Committee (Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 2071048285; bloomsbury.rec@hra.nhs.uk), ref: 12/LO/0568

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Colorectal polyps

Interventions
Study participants will be randomised to receive either prophylactic application of PuraStat® to the EMR base (treatment group) or standard treatment (no PuraStat®, control group). Intraprocedural bleeding will be dealt with as per standard practice. All equipment needed to deliver thermal therapy will be ready during the entirety of the procedure thereby ensuring no delay in administration should it need to be used. Patient safety and care remains paramount and will not be compromised in this situation.

All therapeutic procedures will be performed by endoscopists with expertise in advanced assessment and resection of GI neoplasia. The endoscopes and all other devices used, including snares, will not be different from those routinely used, and are all CE approved.

After randomisation, the EMR resection technique will not be different from the standard technique.

Bowel preparation will be administered in line with the usual departmental guidelines.

All patients will have telephonic follow up at 1-7 days and then at 30 days (+/- 14 days) following the EMR procedure. Patients will be advised on how to seek medical help and how to notify the research team if bleeding occurred in the community.

Delayed bleeding will be treated according to routine clinical practice.

All these patients will have endoscopic follow up as per routine clinical practice (i.e. at 3-6 months, and at 12 months following EMR).

Sample size: 270 patients per group for a total of 540 subjects. After 75% of the planned subjects have been treated and completed the primary efficacy endpoint evaluation a single interim analysis will occur, during which the sample size may increase, but to no more than double the original sample size (540 per group, 1080 subjects)

Follow up duration is 30 days (+/- 14 days)

Planned study period is 2 years

Intervention is PuraStat® applied prophylactically to EMR base. Control is Standard treatment with no PuraStat®

Intervention Type
Other

Primary outcome(s)
Delayed bleeding rate. Delayed bleeding is defined as bleeding after 24 hours but within 28 days of the procedure, which can be directly attributed to the EMR, resulting in hospital admission, significant HB drop (≥2 points), haemodynamic compromise, and/or need for endoscopic, radiological or surgical intervention or blood transfusion.

Key secondary outcome(s))
1. Rate of post polypectomy syndrome post EMR (pain, discomfort, fever, raised inflammatory markers) measured using standard pain scale, thermometer and blood tests at within 28 days post EMR
2. Amount of PuraStat® used (in MLS) measured using Purastat® syringe at time of Purastat® application during EMR procedure
3. Duration of time (in seconds) required to apply PuraStat® measured using a stop watch at time of Purastat® application during EMR procedure

Completion date
08/12/2024

Eligibility

Key inclusion criteria
1. Adult (aged 18 years or above at time of recruitment) patients referred for EMR of colorectal polyps
2. Polyp size: 20 mm or more
3. Polyp location:
3.1. Proximal colon: All non-pedunculated polyps ≥20 mm
3.2. Distal colon: All non-pedunculated polyps ≥20 mm and patient is on antiplatelet and/or anticoagulation
4. Participant is willing and able to give informed consent for participation in the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Adenoma with known (histologically confirmed) carcinoma
2. Coagulopathy (INR ≥1.5, platelets <50)
3. Poor bowel preparation
4. Patients who, according to Investigator’s opinion, should not be included in the study for any reason, including inability to follow study procedures, e.g. cognitively impaired, debilitated or frail patients

Date of first enrolment
09/12/2021

Date of final enrolment
08/06/2023

Locations

Countries of recruitment
United Kingdom

England

Italy

Spain

Study participating centre
Queen Alexandra Hospital
Southwick Hill Road
Cosham
Portsmouth
United Kingdom
PO6 3LY

Study participating centre
Kings College Hospital
Mapother House
De Crespigny Park
Denmark Hill

London
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SE5 8AB

Study participating centre
Queen's Medical Centre, Nottingham University Hospital NHS Trust
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Headley Way
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OX3 9DU

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Gloucestershire Royal Hospital
Great Western Road
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GL1 3NN

Study participating centre
University College Hospital
235 Euston Road
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NW1 2BU

Study participating centre
St George's University Hospital
Cranmer Terrace
London
United Kingdom
SW17 0RE

Study participating centre
Humanitas Research Hospital
Milan
Italy
-

Study participating centre
Complejo Hospitalario de Navarra
Pamplona
Spain
-

Study participating centre
Hospital Clinic
Barcelona
Spain
-

Sponsor information

Organisation
Portsmouth Hospitals NHS Trust

ROR
https://ror.org/009fk3b63

Funder(s)

Funder type
Industry

Funder Name
3-D Matrix, Ltd

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date