ISRCTN15269750 https://doi.org/10.1186/ISRCTN15269750

Results after endoscopic removal of colorectal lesions using an advanced energy device

Submission date	Recruitment status	[_] Prospectively registered
06/03/2023	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
11/03/2023	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
09/03/2023	Digestive System	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Speedboat-assisted endoscopic submucosal dissection (SSD) is a technique that utilizes a special endoscopic instrument (the Speedboat™) to remove lesions in the colon and rectum in one piece. The performing doctor inserts the Speedboat™ device via the telescope/endoscope during the colonoscopy procedure. At the end of the procedure, the polyp will be removed entirely in one piece, pinned out to a hard board and sent to the lab for an accurate histological /microscopic assessment. This study aims to assess the clinical short- and long-term outcomes of all patients who underwent Speedboat-assisted endoscopic submucosal dissection in East Kent Hospitals University NHS Foundation Trust.

Who can participate?
Patients aged over 18 years with a colon/rectum lesion with a recommendation to use the ESD technique to remove the lesion

What does the study involve?
The collected data will include patients' medical history, polyps' characteristics, specific technical details, any complications and short- and long-term outcomes.

What are the possible benefits and risks of participating?
This study will help to find out who will benefit the most from SSD removal of polyps as well as monitor any complications and measure clinical outcomes. Removing these lesions will prevent colorectal cancer. There are no added risks of participating in this study apart from the established and recognised risks of endoscopic en-bloc (one piece) removal of the lesion. This is part of the patient's standard of care.

Where is the study run from?
Queen Elizabeth the Queen Mother Hospital (UK)

When is the study starting and how long is it expected to run for?
January 2018 to January 2024

Who is funding the study?
East Kent University Hospitals NHS Foundation Trust (UK)

Who is the main contact?
1. Zacharias Tsiamoulos, ztsiamoulos@nhs.net
2. Mr Shady Zeidan, s.zeidan@nhs.net

Contact information

Type(s)
Principal investigator

Contact name
Dr Zacharias Tsiamoulos

ORCID ID
https://orcid.org/0000-0003-0235-7110

Contact details
Queen Elizabeth The Queen Mother Hospital
St Peters Road
Margate
United Kingdom
CT9 4AN
+44 (0)1843225544
ztsiamoulos@nhs.net

Type(s)
Scientific

Contact name
Mr Shady Zeidan

ORCID ID
https://orcid.org/0000-0002-5153-0437

Contact details
William Harvey Hospital
Kennington Rd, Willesborough
Ashford
United Kingdom
TN24 0LZ
+44 (0)1233 633331
s.zeidan@nhs.net

Type(s)
Scientific

Contact name
Dr Muneer Abbas

Contact details
Queen Elizabeth the Queen Mother Hospital
St Peter's Lane
Margate
United Kingdom
CT4 9AN
+44 (0)1843225544
muneer.abbas@nhs.net

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil Known

Protocol serial number
RN800372

Study information

Scientific Title
Speedboat-assisted endoscopic submucosal dissection - clinical outcomes

Acronym
SSD Clinical Outcomes

Study objectives
Speedboat™ Inject device is a CE-marked endo-surgical device that allows safe tissue cutting and coagulation in the gastrointestinal (GI) tract. Using special electrocautery properties (Bipolar Radiofrequency), tiny cuts underneath the polyp surface are made to separate it from the bowel wall. Any blood vessels that feed the polyp are sealed using a different type of coagulation (high-frequency microwave). It facilitates a swift Endoscopic Submucosal Dissection (ESD) with a small risk of bleeding or perforation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/03/2022, the audit department at East Kent University Hospitals NHS Foundation Trust (Clinical Audit Office, Kent and Canterbury Hospital, Ethelbert Road, Canterbury, Kent, CT1 3NG, UK; +44 (0)1227 864300 ext 722 2010; ekh-tr.ClinicalAudit@nhs.net), ref: RN800372

Study design
Prospective observational cohort audit

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Consecutive patients with colorectal polyps referred from the complex polyp multi-disciplinary meeting to remove polyps and prevent bowel cancer

Interventions
Endoscopic treatment with submucosal dissection of colorectal polyps.

A prospective cohort of colorectal Speedboat-assisted Submucosal Dissection (SSD) cases is initiated for a duration of 6 years, lined up with STROBE guidelines. One experienced operator will perform all cases. Short and long-term clinical outcomes are recorded. Simple and multiple linear regression statistical analysis will be used to explore whether factors, such as polyp size /surface/location/morphology could impact the duration of the procedure. Cost analysis from the hospital perspective will be also conducted.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Rate of complete resection: measuring the number of polyps (percentage) that were completely removed en-bloc (in one piece) to the total number of polyps removed. The rate is compared to the standard benchmark rate of >90%.
1.1. Clinical complete resection is identified during the procedure by the complete removal of the lesion as recorded by the operating physician. Data source: Electronic patients' medical records such as Endoscopy reporting software within the Trust - UniSoft from 01/01/2018 till 30 /06/2022 and Solus from 01/07/2022 and onwards. Data recorded on the reporting software at the time of the procedure. Data collection between 01/01/2018 to 01/01/2024.
1.2. Histological complete resection is identified during histological examination of the excised lesion by a consultant histopathologic. Data source: Electronic patients' medical records such as Histology reporting software within the Trust - APEX/DART system and Sunrise. Data recorded at the time of histological assessment on APEX. Typically 2-3 weeks after the procedure. Data collection between 01/01/2018 to 01/01/2024.
2. Rate of conversion to piecemeal resection: measuring the number of polyps (percentage) that were NOT completely removed en-bloc (in one piece) to the total number of polyps removed. The rate is compared to the standard benchmark rate of <10%. Conversion to piecemeal is identified during endoscopic excision of the lesion as recorded by the operating physician on the endoscopy report on the day of the procedure. Data source: Endoscopy reporting software, Unisoft from 010/01/2018 and Solus from 01/07/2022 and onwards unitil 01/01/2024.
3. Rate of immediate complications: measuring the number of patients (percentage) who developed one or more of: intra-procedural bleeding (i.e. within 24 hours of the procedure), perforation (tear of the bowel wall), unplanned admission or any other adverse events /unplanned intervention (like surgery) to the total number of patients.
3.1. Intra-procedural and early bleeding is noted EITHER during the procedure by the operating physician OR reported by patients/health care professionals in the first 24 hours after the procedure. Data source: Unisfot/Solus - data recorded on the reporting system at the time of procedure OR Patient electronic medical records (Sunrise system at EKHUFT) within 24 hours of the procedure. From 01/01/2018 till 01/01/2024.
3.2. Perforation is identified during the endoscopic excision of the lesion by the operating physician. Data source: Endoscopy reporting software within the Trust - UniSoft from 01/01

/2018 till 30/06/2022 and Solus from 01/07/2022 and onwards till 01/01/2024. Data recorded on the reporting software at the time of the procedure.
3.3. Unplanned admission: If an unplanned admission took place within 24 hours of the procedure, an inpatient episode is recorded on PAS.
3.4. Unplanned intervention: If an unplanned intervention took place within 24 hours of the procedure, this will be documented on the electronic medical records (Sunrise) as well as on the theatre electronic records (Theatreman). From 01/01/2018 till 01/01/2024.
4. Rate of delayed complications: measuring the number of patients (percentage) who developed one or more of: delayed complications (i.e. after 24 hours of the procedure) delayed bleeding, delayed perforation (tear of the bowel wall), unplanned admission or any other unplanned intervention (like surgery) to the total number of patients.
4.1. Delayed bleeding: measured by the presence of bleeding as reported by patients or health care professionals involved in patient's care - recorded on electronic medical records (Sunrise) AFTER 24 hours of the procedure. From 01/01/2018 till 01/01/2024
4.2. Delayed perforation: measured by the presence of perforation AFTER 24 hours of procedure confirmed by clinical examination by an experienced physician (documented in electronic medical records (data source: Sunrise)) and by imaging modality (e.g. CT scan) as reported by an experienced radiologist (data source - PACS imaging system). From 01/01/2018 till 01/01/2024
4.3. Unplanned admission: If an unplanned admission took place after 24 hours of the procedure, an inpatient episode is recorded on PAS (data source PAS)
4.4. Unplanned intervention: If an unplanned intervention took place after 24 hours of the procedure, this will be documented on the electronic medical records (data source: Sunrise) as well as on the theatre electronic records (data source: Theatreman). From 01/01/2018 till 01/01/2024
5. Surveillance frequency: measuring the number of endoscopies at 6 months, 1 year and 3 years as per the British Society of Gastroenterology guidelines to check for recurrence. Measured using the number of endoscopy checks as documented on endoscopy reporting systems (data source: Unisoft and Solus) at 6 months, 1 year and 3 years after the procedure.
From 01/01/2018 till 01/01/2024.
6. Long-term outcome: measuring the local polyp tissue recurrence rate (number of patients with recurrence of polyp to the total number) and survival rate at 3 years.
6.1. Local recurrence: measured by the presence of polyp tissue recurrence during endoscopy check as reported by the endoscopist on the reporting system. Data source: Unisoft/Solus at 6 months, 1 year and 3 years after the procedure. From 01/01/2018 till 01/01/2024
6.2. Survival/mortality rate: patients who died within 3 years of the procedure will be identified using electronic medical records (Sunrise - date of death is documented on the system at the time of death). From 01/01/2018 till 01/01/2024.

Key secondary outcome(s))

1. Polyp size/surface/location/morphology as documented on the endoscopy report on the day of the procedure from Unisoft/Solus. From 01/01/2018 till 01/10/2024
1.1. Polyp size: each polyp is measured twice by the operating physician after the resection is completed and by the histopathologist before histological assessment. Two measurements of two axes are taken using a ruler after the lesion is pinned to a cork sheet - the longest axis (axis 1) and the one perpendicular to it (axis 2). Source: Endoscopy reporting system (Unisoft/Solus) recorded at time of procedure AND histology reporting system (Apex - typically within 2-3 weeks of procedure).
1.2. Polyp surface: assuming that most polyps are nearly oval in shape, the formula of oval surface is used to calculate the surface - (Axis 1 * Axis 2)/2 * 3.14
1.3. Polyp location and morphology: identified by the operating physician and recorded on Unisoft/Solus at the time of the procedure.

1.4. Time of procedure: recorded by the operating physician and recorded on Unisoft/Solus at end of the procedure. From 01/01/2018 till 01/01/2024
2. Cost analysis from the hospital and NHS perspective conducted using data from the Finance Department of EKHUFT. Cost analysis will combine data from multiple systems within the Trust to provide cost calculations for each case. Sources are: Patient level data – PAS; Theatre data – Theatreman; Imaging – RIS; Pathology – APEX; Drugs – JAC; Endoscopy – Unisoft/ SOLUS (new system from July 2022). From 01/01/2018 till 01/01/2024

Completion date
01/01/2024

Eligibility

Key inclusion criteria
1. Aged >18 years old
2. Lower GI lesion - colon and rectum
3. Lesion of any size and any pathology
4. Discussed in the complex polyp multi-disciplinary with a recommendation to use the ESD technique to remove the lesion
5. Speedboat-assisted ESD technique to be used to remove the lesion

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Age <18 years
2. Pregnancy
3. Upper GI lesion - oesophagus, stomach, duodenum and small bowel
4. Lesions removed by other techniques (i.e. not by ESD) as planned by the complex polyp multi-disciplinary meeting
5. Lesions not discussed at the complex polyp multi-disciplinary meeting

Date of first enrolment
01/01/2018

Date of final enrolment
01/01/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Queen Elizabeth the Queen Mother Hospital
St Peters Road
Margate
United Kingdom
CT9 4AN

Sponsor information

Organisation
East Kent Hospitals University NHS Foundation Trust

ROR
https://ror.org/02dqqj223

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
East Kent Hospitals University NHS Foundation Trust

Results and Publications

Individual participant data (IPD) sharing plan
Data will be stored on East Kent Hospitals University NHS Foundation Trust (EKHUFT)'s secured computer which is not publicly available. This data has patient confidential data and therefore it will remain saved in a trusted shared drive within the EKHUFT IT system. The dataset will not be made available to protect patients' confidentiality unless the audit department in EKHUFT provides authorisation if the data is required to be shared.

IPD sharing plan summary

Stored in non-publicly available repository, Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			07/03/2023	No	No