

From: "CLINICALAUDIT (EAST KENT HOSPITALS UNIVERSITY NHS FOUNDATION TRUST)" <ekh-tr.ClinicalAudit@nhs.net>
Subject: RN800372

From: Clinical Audit <ekh-tr.ClinicalAudit@ekhuft.nhs.uk>
Sent: 28 February 2022 14:31
To: CLINICALAUDIT (EAST KENT HOSPITALS UNIVERSITY NHS FOUNDATION TRUST) <ekh-tr.ClinicalAudit@nhs.net>
Subject: FOR ACTION: Proposal Submitted

Clinical Audit - Proposal form : RN800372 Proposal Submitted

Please action this form submitted by Shady Zeidan. [Click here to respond.](#)

Project overview	
Project title	Speedboat Endoscopic Submucosal Dissection - Clinical Outcome Audit
Is this topic a Trust priority, in line with the Care Group Quality Profile?	Yes
Do you feel this proposal is a Clinical Audit or a QIP?	Clinical Audit

Please confirm the Specialty Audit Lead has approved the audit and agreed to add it to the Audit Programme		Yes	
Proposed schedule			
Proposal submitted	28/02/2022	Analysis complete	01/02/2024
Data collection - start	01/01/2018	Draft report	01/03/2024
Data collection - finish	01/01/2024	Final report	01/04/2024
Contact details of person taking responsibility for this project			
Full name		Shady Zeidan (s.zeidan@nhs.net)	
Email		s.zeidan@nhs.net	
Grade		Consultant	
Site		QEQM	
Phone/mobile		07737612388	

Name of Educational Supervisor if in training		Zacharias Tsiamoulos - Endoscopy lead and supervisor for the complex polyp fellowship	
Project details			
Doctors	Yes	Child/ Women's Health	No
Specify Doctors involved	Joseph Sebastian - Consultant Surgeon	Specify Child/ Women's Health involved	
Managers	No	Emergency Medicine	No
Specify managers involved		Specify Emergency Medicine involved	
Matrons	No	Radiologists	No

		Specify radiologists involved	
Nursing staff	Yes	Surgical services	No
Specify nursing staff involved	Simona Gamble - Complex Polyp Specialist Nurse	Specify surgical services involved	
Palliative Care	No	Therapists	No
		Specify therapists involved	
Pharmacists	No	External Personnel	No
Specify pharmacists involved		Specify external personnel involved	

Other	Yes	Specify any other parties involved	James Spinner Complex Polyp MDM Co-ordinator Soad Elkady - Complex polyp trainee Polychronic Gatopoulos - Complex polyp trainee
Have the Stakeholders agreed to be involved with this project?		Yes	
Scope of audit		Trust wide	
If other, please detail			
Clinical risk/ complaint		Reference	

National Guideline	Yes	Reference	BSG/ACPGBI guidelines for the management of large non-pedunculated colorectal polyps. Rutter MD, et al. Gut 2015;0:1–27. doi:10.1136/gutjnl-2015-309576.
NICE Guidance / Quality Standard	Yes	Reference	Endoscopic submucosal dissection of lower gastrointestinal lesions. IPG335
Patient Suggestion	No	Reference	
Trust Guideline		Reference	

Other	Yes	Referen ce	<p>Pimentel-Nunes Pedro et al. Endoscopic submucosal dissection: ESGE Guideline... Endoscopy 2015; 47: 829–854 AND Japan Gastroenterological Endoscopy Society guidelines for colorectal endoscopic submucosal dissection/ endoscopic mucosal resection. Shinji Tanaka et al. Digestive Endoscopy 2020; 32: 219–239 doi: 10.1111/den.13545</p>
	<p>Speedboat is an endo-surgical device that allows a safe tissue cutting and coagulation in the gastrointestinal (GI) tract. It facilitate a swift Endoscopic Submucosal Dissection (ESD) with a smaller risk of</p>		

(ESD) with a smaller risk of bleeding or perforation.

The audit aims to assess the clinical short and long term outcomes of all patients who underwent Speedboat ESD in EKHUFT.

Main clinical outcome - Rate of en-block resection.

An en-block resection is the best indicator of cure for patients with complex pre-cancerous or superficially cancerous polyps in the colon and rectum. This will confirm the efficacy of this technique.

Project objective(s)

Other outcomes will help confirming the safety profile of the procedure, adequate long term outcomes and the assessment of the health-economic benefits of utilising the device.

Specifically these outcomes are:

1. Rate of complete resection
2. Rate of conversion to piecemeal resection
3. Rate of immediate complications - Bleeding

	<p>complications -- Bleeding, perforation, unplanned admission, other adverse events and unplanned intervention</p> <p>4. Rate of delayed complications -- Bleeding, perforation, Re-admission, other adverse events and unplanned procedure</p> <p>5. Surveillance frequency</p> <p>6. Long term outcome -- local recurrence and survival</p> <p>7. Health-economic analysis</p>
	<p>BSG Guidelines:</p> <p>We recommend that endoscopic resection should be first-line therapy for the removal of LNPCPs where there is no suspicion of malignancy (suspicion of malignancy as defined in these guidelines) (GRADE of evidence: moderate; Strength of recommendation: strong).</p> <p>– We recommend that piecemeal resection (either endoscopic or surgical) should be avoided if malignancy is suspected (GRADE of evidence: low; Strength of recommendation: strong).</p> <p>Key performance indicators</p>

Specific Clinical Audit Criteria

key performance indicators (KPIs) for ESD

- en-block resection rate

>90%

- Perforation rate - - Bleeding rate - - Recurrence rate -

European Society of Gastrointestinal Endoscopy Guidelines:

ESGE states that the majority of colonic and rectal superficial lesions can be effectively removed in a curative way by standard polypectomy and/or by EMR (strong recommendation, moderate quality evidence).

ESD can be considered for removal of colonic and rectal lesions with high

suspicion of limited

submucosal invasion that is

based on two main criteria of

depressed morphology and

irregular or nongranular

surface pattern, particularly

if the lesions are larger than

20 mm; or ESD can be

considered for colorectal

lesions that otherwise cannot

be optimally and radically

removed by

snare-based techniques

(strong recommendation,

moderate quality evidence)

Project methodology	
Data collection will be undertaken	Concurrently
Inclusion criteria for patient cohort	<p>Adults - Age >18 years old</p> <p>Lower GI lesion - Colon and Rectum.</p> <p>Lesion of any size and any pathology.</p> <p>Discussed in the Complex polyp MDM with recommendation to use ESD technique to remove the lesion</p> <p>Speedboat ESD technique used/attempted to remove of the lesion</p>
Exclusion criteria for patient cohort	<p>Age Upper GI lesion - Oesophagus, Stomach, Duodenum and Small bowel</p> <p>Lesions removed by other technique (Not by ESD) or other devices (Not by Speedboat)</p>
Cases to be identified by	<p>Complex Polyp MDM referrals and outcomes</p> <p>UniSoft GI Reporting tool</p> <p>Theaterman</p> <p>Clinical letters from Patient</p> <p>Electronic Records</p>

Proposed time period cases to be drawn from	<p>This is an ongoing audit of the clinical outcomes of the Speedboat ESD Technique from January 2018.</p> <p>The audit will continue concurrently with a proposed finish date in January 2024. By the end of this period, further audit proposal will be submitted to continue the concurrent collection of data.</p>
Proposed number of cases	<p>We expect a minimum of 25 cases per year.</p> <p>A cumulative number from 2018 to 2024 is expected to be at least 125 cases.</p>
Estimated TOTAL population size	At least 125 cases over the 5 years period.
Could the data for this project be collected electronically on a tablet/ iPad/smartphone?	Yes
Will data be captured from electronic systems such as EDN, VitalPAC, eCascards?	Yes
Will paper patient notes be required for data collection?	No

What sources will be used to gather data		UniSoft Reporting Tool VitalPAC PACS Electronic Discharge Notification (EDN) Dart	
Is assistance required?	No	Obtaining patient list	No
Data analysis	No	Advice/guidance	No
Obtaining patient hospital notes	No	Report writing	No
Developing questionnaire	No	Data entry/validation	No
Creating a presentation	No	Action planning	No
Declarations			

I confirm that the information provided is accurate to the best of my knowledge	Yes
Staff name	Shady Zeidan
Care Group	General and Specialist Medicine
Care Group meeting approved at	With Dr Tsiamoulos
Date of meeting	28/02/2022
Named representative of group	Zacharias Tsiamoulos (ztsiamoulos@nhs.net)
Named representative Job Title	Consultant
Named representative Email Address	ztsiamoulos@nhs.net

--

This message may contain confidential information. If you are not the intended recipient please inform the sender that you have received the message in error before deleting it.

Please do not disclose, copy or distribute information in this e-mail or take any action in relation to its contents. To do so is strictly prohibited and may be unlawful. Thank you for your co-operation.

EKHUFT - K2

This message originated from outside of NHSmail. Please do not click links or open attachments unless you recognise the sender and know the content is safe.