# Does having regular follow-up after surgery lead to early detection of the cancer returning, resulting in improved survival and better quality of life in patients who have had gullet or gastric cancer removal?

Submission date	<b>Recruitment status</b> Recruiting	[X] Prospectively registered		
23/01/2023		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
14/03/2023	Ongoing	Results		
Last Edited	Condition category	Individual participant data		
16/10/2025	Cancer	[X] Record updated in last year		

#### Plain English summary of protocol

https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-to-see-if-more-frequent-follow-up-is-better-for-people-with-oesophageal-cancer-and

#### Background and study aims

There are over 15,800 new cases of gullet (oesophageal) or stomach cancer diagnosed every year in the UK, with over 12,300 deaths per year attributed to these cancers. Currently, most patients with cancer of the gullet and stomach are treated with surgery with or without additional chemo- or radio-therapy. In recent years there have been improvements in survival from these two cancers due to better therapies, less invasive surgery and earlier detection. Despite these improvements, in around two-thirds of patients treated with surgery, the cancer will return and lead to death within 3 years.

At present there is very little evidence as to how gullet and stomach cancer patients should be followed up after surgery and whether different methods of follow-up could improve survival. Currently, national and international guidelines do not provide consistency in their recommendations for follow-up after surgery.

After surgery for gullet or stomach cancer, normally patients would have a post-surgical clinic visit with their hospital around 4 to 8 weeks after their operation and then another follow-up at 6 months and 12 months after the operation. In this study, the researchers want to see if it is beneficial to patients to have more frequent clinical reviews and scans after this type of cancer surgery. This study will investigate whether more regular radiological scans can lead to earlier detection of a cancer returning, at a stage when it may be more readily treatable. This means that participants who agree to take part will be allocated by chance to either more intensive surveillance (including regular radiological scans and a camera test [endoscopy]) or the current standard of care. The main aim of this study will be to determine whether earlier detection of cancer through more intensive follow-up results in improved survival and better quality of life for patients with gullet or stomach cancer.

Who can participate?

Patients aged 16 years or over who have been treated with surgery for gullet and stomach cancer at around 4 to 8 weeks after their surgery

#### What does the study involve?

If the patient agrees to join the study, she/he will be asked to sign the SARONG study consent form. A member of the study team will then ask about the patient's medical history and medications, and collect some information from the patient's medical records about their diagnosis and surgery and ongoing treatment. The patient will be asked to fill in some questionnaires about their health-related quality of life. The patient can decide if he/she would like to fill in the questionnaires on paper or online via a secure study website. Patients will then be randomly allocated into either group 1 (standard of care: normal clinical visit schedule) or group 2 (intervention: extra clinical visits with scans and an endoscopy). The standard care group will receive a review in clinic or by telephone at 6 and 12 months. After this they will be either discharged to their local doctor or receive a review in clinic with a member of the surgical team every year.

The intensive surveillance group will receive a review in clinic or by telephone with a member of the surgical team, and a radiological scan at 6, 12, 18, 24, 30 and 36 months later. They will also receive an endoscopy 12 months later.

What are the possible benefits and risks of participating?

Consultation with patient groups and charities, including Heartburn Cancer UK, Oesophageal and Stomach Cancer Patient Support group, Action against Heartburn UK, and GUTS charity UK, has taken place and patients will continue to be integral to the organisation and running of the study. The findings will be presented at national and international meetings, published in a high-impact scientific journal and disseminated with a broader social media strategy. All participants taking part in the study will be informed of the findings via the study website. The researchers anticipate that the results of the study may have a significant practice-changing impact on patients undergoing follow-up after surgery for gullet and stomach cancer.

There may be no direct benefit to the patient as a result of taking part in this study, however, if the patient is allocated to group 2 and have more regular visits including scans and an endoscopy this may result in detecting any cancer returning sooner. In addition, it is hoped that the information gained from this study will help to understand how to better follow up people treated for oesophageal and stomach cancer in the future.

Participants allocated to group 2 will have additional CT scans of their chest, abdomen and pelvis, and clinical visits, which will involve additional time in the hospital as an outpatient. CT scans use ionising radiation to form images of the body and/or provide the doctor with other clinical information. Ionising radiation can cause cell damage that may, after many years or decades, turn cancerous. The chances of this happening to a patient as a consequence of taking part in this study are 0.5%.

Patients will also have an upper gastrointestinal endoscopy at 12 months; this procedure does carry the potential risk of injury to the oesophagus or stomach (less than 5 in 100).

Where is the study run from? University of Oxford (UK)

When is the study starting and how long is it expected to run for? September 2022 to April 2029

Who is funding the study?
National Institute for Health and Care Research (NIHR) Health Technology Assessment (HTA)
Programme (UK)

Who is the main contact? SARONG Trial Manager sarong@nds.ox.ac.uk

## Contact information

#### Type(s)

Principal investigator

#### Contact name

Prof Sheraz R Markar

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## Additional identifiers

#### Clinical Trials Information System (CTIS)

Nil known

#### Integrated Research Application System (IRAS)

319230

#### ClinicalTrials.gov (NCT)

Nil known

#### Protocol serial number

IRAS 319230, NIHR134344, CPMS 55905

# Study information

Scientific Title

Open-label randomised controlled trial of intensive surveillance vs standard postoperative follow-up in patients undergoing surgical resection for oesophageal and gastric cancer: the Surveillance After Resection of Oesophageal and Gastric cancer (SARONG) trial

#### Acronym

**SARONG** 

#### **Study objectives**

This trial aims to see if additional surveillance improves mortality and health-related quality of life (HRQoL) in participants with oesophageal or gastric cancer compared to current standard of care.

#### Ethics approval required

Ethics approval required

#### Ethics approval(s)

approved 02/05/2023, North West - Haydock Research Ethics Committee (3rd Floor - Barlow House, 4 Minshull Street, Manchester, M1 3DZ, United Kingdom; +44 (0)2071048032, +44 (0) 2071048248; haydock.rec@hra.nhs.uk), ref: 23/NW/0104

#### Study design

Multi-centre open-label two-arm parallel-design superiority randomized controlled trial

#### Primary study design

Interventional

#### Study type(s)

Treatment

#### Health condition(s) or problem(s) studied

Oesophageal or gastric cancer

#### **Interventions**

Participants will be randomized by the local study team via a centralised validated computer randomisation program through a secure (encrypted) web-based service, RRAMP (https://rramp.octru.ox.ac.uk), provided by the Oxford Clinical Trials Research Unit (OCTRU), accessed via the SARONG REDCap study database.

Participants will be randomized in a 1:1 ratio to one of the following treatment arms:

- 1. Follow-up with intensive surveillance (intervention arm): Intensive surveillance (including radiological [CT] scans [chest and abdomen]) every 6 months for 36 months and endoscopy at 12 months post-randomisation
- 2. Usual care follow-up (control arm): Standard of care follow-up for 36 months

Upon randomization of a participant, the OCTRU SARONG study office and a member of the site research team will be notified by an automated email.

Full details of the randomization procedure will be stored in the Randomization and Blinding Plan in the confidential statistical section of the Trial Master File (TMF).

#### Intervention Type

#### Primary outcome(s)

All-cause mortality, defined as death from any cause. Participants who have not been observed to die during the course of the study will have their survival time censored at their last known follow-up date (evaluated at 3 years post-randomisation of the last included participant)

#### Key secondary outcome(s))

- 1. Disease-specific mortality, defined as known oesophageal or gastric cancer recurrence at the time of death, evaluated using the participant's medical notes at 3 years post-randomisation of the last included participant
- 2. Pattern of tumour recurrence, defined as the incidence of loco-regional or distant recurrence, evaluated using the participant's medical notes including CT reports at 3 years post-randomisation of the last included participant
- 3. Treatment of tumour recurrence, i.e. the requirement for chemotherapy, surgery, immunotherapy, radiotherapy, chemoradiotherapy, best supportive care or other as determined by the clinical team at the treating site, evaluated using the participant's medical notes at 3 years post-randomisation of the last included participant
- 4. Rates of oligometastatic (one site) tumour recurrence evaluated using the participant's medical notes including CT reports at 3 years post-randomisation of the last included participant 5. Rates of multi-metastatic (several sites) tumour recurrence evaluated using the participant's medical notes including CT reports at 3 years post-randomisation of the last included participant 6. Health-related quality of life, including anxiety or depression and worry of cancer returning, measured by the following validated questionnaires:
- 6.1. EQ-5D-5L
- 6.2. EORTC QLQ-C30
- 6.3. EORTC QLQ-OG25
- 6.4. Cancer Worry Scale

Participant-reported outcome (questionnaires administered and data collected centrally) at baseline, 6, 12, 18, 24, 30 and 36 months post-randomisation.

7. Incremental cost per quality-adjusted life year (QALY): participant-reported outcome (questionnaires administered and data collected centrally) and participant's medical records for resources used in secondary care collected at baseline 6, 12, 18, 24, 30 and 36 months post-randomisation.

#### Completion date

30/04/2029

## **Eligibility**

#### Key inclusion criteria

A patient will be eligible for inclusion in this study if all of the following criteria apply:

- 1. Has undergone surgical resection for curatively intended treatment of oesophageal or gastric cancer (adenocarcinoma and squamous cell carcinoma) with or without neoadjuvant/adjuvant chemotherapy or radiotherapy or immunotherapy (or in combination).
- 2. Aged 16 years or over
- 3. Willing and able to give informed consent

#### Participant type(s)

Patient

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

16 years

#### Sex

All

#### Key exclusion criteria

A patient with not be eligible for the trial if ANY of the following apply:

1. Has other cancers undergoing treatment or surveillance for this cancer

#### Date of first enrolment

09/06/2023

#### Date of final enrolment

30/04/2026

#### Locations

#### Countries of recruitment

United Kingdom

England

Northern Ireland

Scotland

Wales

#### Study participating centre

## Oxford University Hospitals NHS Foundation Trust

Churchill Hospital Old Rd Headington Oxford United Kingdom OX3 7LE

Study participating centre Imperial College Healthcare NHS Trust

The Bays

St Marys Hospital South Wharf Road London United Kingdom W2 1BL

#### Study participating centre Guy's and St Thomas' NHS Foundation Trust

Westminster Bridge Rd London United Kingdom SE1 7EH

#### Study participating centre Nottingham University Hospitals NHS Trust

Queens Medical Centre Derby Road Nottingham United Kingdom NG7 2UH

#### Study participating centre Leeds Teaching Hospitals NHS Trust

St. James's University Hospital Beckett Street Leeds United Kingdom LS9 7TF

#### Study participating centre Royal Surrey County Hospital NHS Foundation Trust

Egerton Road Guildford United Kingdom GU2 7XX

## Study participating centre Brighton and Sussex University Hospitals NHS Trust

Royal Sussex County Hospital Eastern Road Brighton United Kingdom BN2 5BE

#### Study participating centre University Hospitals of North Midlands NHS Trust

Newcastle Road Stoke-on-trent United Kingdom ST4 6QG

#### Study participating centre

University Hospitals Birmingham NHS Foundation Trust

Queen Elizabeth Hospital
Mindelsohn Way
Edgbaston
Birmingham
United Kingdom
B15 2GW

#### Study participating centre South Tees Hospitals NHS Foundation Trust

James Cook University Hospital Marton Road Middlesbrough United Kingdom TS4 3BW

# Study participating centre Northern Care Alliance NHS Foundation Trust

Salford Royal Stott Lane Salford United Kingdom M6 8HD

# Study participating centre University Hospitals Bristol and Weston NHS Foundation Trust

Trust Headquarters Marlborough Street Bristol United Kingdom BS1 3NU

#### Study participating centre University Hospitals Coventry and Warwickshire NHS Trust

Walsgrave General Hospital Clifford Bridge Road Coventry United Kingdom CV2 2DX

# Study participating centre Portsmouth Hospitals University NHS Trust

Cambridge House Queen Alexandra Hospital Southwick Hill Road Portsmouth United Kingdom PO6 3LY

#### Study participating centre University Hospitals Southampton NHS Foundation Trust

Tremona Road Southampton United Kingdom SO16 6YD

# Study participating centre Norfolk and Norwich University Hospitals NHS Foundation Trust

Colney Lane Colney Norwich United Kingdom NR4 7UY

#### Study participating centre Belfast Health and Social Care Trust

Belfast City Hospital Lisburn Road Belfast United Kingdom BT9 7AB

#### Study participating centre Royal Infirmary Hospital Edinburgh

51 Little France Cres, Old Dalkeith Rd Edinburgh United Kingdom EH16 4SA

#### Study participating centre University Hospitals of Leicester NHS Trust

Leicester Royal Infirmary Infirmary Square Leicester United Kingdom LE1 5WW

#### Study participating centre University Hospitals Plymouth NHS Trust

Derriford Rd Plymouth United Kingdom PL6 8DH

# Study participating centre Mid and South Essex NHS Foundation Trust

Prittlewell Chase Westcliff-on-sea United Kingdom SSO ORY

## Study participating centre

University Hospitals of Derby and Burton NHS Foundation Trust

Royal Derby Hospital Uttoxeter Road Derby United Kingdom DE22 3NE

# Study participating centre East Kent Hospitals University NHS Foundation Trust

Kent & Canterbury Hospital Ethelbert Road Canterbury United Kingdom CT1 3NG

#### Study participating centre United Lincolnshire Hospitals NHS Trust

Lincoln County Hospital Greetwell Road Lincoln United Kingdom LN2 5QY

#### Study participating centre NHS Greater Glasgow and Clyde

Glasgow Royal Infirmary 84 Castle St Glasgow United Kingdom G4 0SF

# Study participating centre Watford General Hospital

60 Vicarage Road Watford United Kingdom WD18 0HB

## Study participating centre

Worcestershire Acute Hospitals NHS Trust

Worcestershire Royal Hospital Charles Hastings Way Worcester United Kingdom WR5 1DD

# Study participating centre Bradford Teaching Hospitals NHS Foundation Trust

Bradford Royal Infirmary Duckworth Lane Bradford United Kingdom BD9 6RJ

#### Study participating centre Yeovil District Hospital NHS Foundation Trust

Yeovil District Hospital Higher Kingston Yeovil United Kingdom BA21 4AT

#### Study participating centre Ipswich Hospital

Heath Road Ipswich United Kingdom IP4 5PD

# Study participating centre Colchester General Hospital

Colchester District General Hosp. Charter Way Turner Road Colchester United Kingdom CO4 5JL

#### Study participating centre The Royal Victoria Infirmary

Queen Victoria Road Newcastle upon Tyne United Kingdom TS1 4LP

#### Study participating centre

#### Cardiff & Vale University Health Board

Heath Park Cardiff United Kingdom CF14 4XW

## Study participating centre Ninewells Hospital

Ninewells Avenue Dundee United Kingdom DD1 9SY

#### Study participating centre Addenbrookes

Addenbrookes Hospital Hills Road Cambridge United Kingdom CB2 0QQ

#### Study participating centre Cheltenham General Hospital

Sandford Road Cheltenham United Kingdom GL53 7AN

# Sponsor information

## Organisation

University of Oxford

#### **ROR**

https://ror.org/052gg0110

# Funder(s)

Funder type

#### **Funder Name**

National Institute for Health and Care Research

#### Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

#### Funding Body Type

Government organisation

#### **Funding Body Subtype**

National government

#### Location

United Kingdom

## **Results and Publications**

#### Individual participant data (IPD) sharing plan

The anonymised master dataset generated by this study will be held as per local CTU policies. It will be available on request from sarong@nds.ox.ac.uk after the final results publication.

#### IPD sharing plan summary

Available on request

#### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			20/09/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes