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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
23/01/2023

Recruitment status
Recruiting

Registration date
14/03/2023

Overall study status
Ongoing

Last Edited
05/06/2025

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[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

Study website
https://sarong.octru.ox.ac.uk/

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
319230

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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
Other

Primary outcome measure
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)

Secondary outcome measures
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.

Overall study start date
01/09/2022

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

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
952

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
31/10/2025

Locations

Countries of recruitment
England

Northern Ireland

Scotland

United Kingdom

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
SS0 0RY

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
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GL53 7AN

Sponsor information

Organisation
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Sponsor details
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+44 (0)1865 616480
RGEA.Sponsor@admin.ox.ac.uk

Sponsor type
University/education

Website
http://www.ox.ac.uk/

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

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

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal. Trial results will be available on the trial website.

Intention to publish date
01/04/2030

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