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Randomised oesophagectomy: minimally invasive or open - comparing different approaches to surgery

Submission date 18/05/2016	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [X] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 31/05/2016	**Overall study status** Completed	
Last Edited 26/03/2024	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-comparing-different-types-of-surgery-for-cancer-of-the-food-pipe-romio-study

Study website
https://bristoltrialscentre.blogs.bristol.ac.uk/details-of-studies/romio/

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number
184167

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
30470

Study information

Scientific Title
ROMIO: Randomised Oesophagectomy - Minimally Invasive or Open

Acronym
ROMIO

Study objectives
Laparoscopically-assisted oesophagectomy (LAO) is superior compared to standard open oesophagectomy (OO) with respect to recovery from surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South West Frenchay Research Ethics Committee, 11/05/2016, ref: 16/SW/0098

Study design
Pragmatic multicentre interventional randomized controlled trial (RCT) with qualitative component

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 the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Oesophageal cancer

Interventions
Patients will be randomised to either open oesophagectomy (OO) or "laparoscopically assisted" oesophagectomy (LAO) using an internet-based randomisation system. Both treatments are provided as standard on the NHS. OO and LAO both consist of identical steps, except that the abdominal phase of the operation in the LAO group will be done through several smaller cuts to the tummy and performed laparoscopically. The duration of treatment is the duration of surgery.

Patients will be followed up using questionnaires for 24-36 months after randomisation into the study (36 month follow-up will only be completed if it falls within the planned length of the study).

Added 18/08/2017:
In Bristol and Southampton patients may be randomised to a third group - Totally Minimally Invasive Oesophagectomy (TMIO). The ROMIO study includes a nested IDEAL Phase 2b study looking at TMIO.

Intervention Type
Procedure/Surgery

Primary outcome measure
Assessment of physical function, using the mean of a subscale of the EORTC QLQ-C30, carried out at 3 and 6 weeks post-surgery and 3 months after randomisation

Secondary outcome measures
1. All cause short and long term complications
2. Impact of the 30-day complications will be categorised using the Clavien-Dindo System
3. Lung function is measured using spirometry measures of forced expiratory volume 1 and forced vital capacity
4. Success of blinding during the first 6 days post-surgery is determined using the Bang Blinding Index procedure
5. Generic and disease specific health-related quality of life measures are determined using EORTC QLQ-C30 and QLQ-OES18, multidimensional fatigue inventory (MFI-20), EuroQOLEQ-5D-5L
6. Quality assurance of surgery with histopathological and surgical measures
6.1. Histopathological measures (with the pathologist assessing these blind to treatment allocation)
6.1.1. Length of the oesophagus
6.1.2. Total count of malignant ‘positive’ nodes
6.1.3. Total count of all nodes
6.1.4. Rates of positive circumferential resection margins
6.1.5. Rates of positive proximal and distal resection margins
6.1.6. pT stage (proportions of patients with each pT stage)
6.2. Surgical measures assessed by a surgeon blind to patient allocation
6.2.1. Quality of abdominal lymphadenectomy
6.2.2. Quality of mediastinal lymphadenectomy
7. Overall and disease-free survival to 2 years
8. Length of hospital stay, defined as length of primary hospital stage plus readmission within 30 days (and length of primary hospital stay plus length of hospital stay if discharged to community hospital).

9. Further measures of resource use including: staff time and resources used in theatre in the interventions; subsequent inpatient stays, outpatient visits, general practitioner visits and other community based resource use

Overall study start date
01/12/2015

Completion date
31/08/2021

Eligibility

Key inclusion criteria
1. 18 years of age or above
2. Referred for primary oesophagectomy by the multi-disciplinary team (MDT) or oesophagectomy following re-staging after neoadjuvant chemotherapy or neoadjuvant chemoradiotherapy (N.B, in this any type of neoadjuvant treatment may be used)
3. Confirmed MDT evidence of at least adenocarcinoma or at least squamous cell cancer of the oesophagus or oesophago-gastric junction
4. Fit for pre-operative anaesthesia and surgery, assessed by the MDT
5. Able to provide written informed consent
6. Measurement (endoscopic or otherwise) that the tumour starts more than 5 cm below crico-pharyngeus
7. Measurement (endoscopic or otherwise) that the tumour involves less than 4 cm of the gastric wall
8. The final pre-treatment tumour stage is between T1N0M0 and T4aN1M0, i.e. including all stages (T1N0M0, T1N1M0, T1N2M0, T2N0M0, T2N1M0, T2N2M0, T3N0M0, T3N1M0, T3N2M0, T4aN0M0 and T4aN1M0) in which T4a is a resectable tumour invading pleura, pericardium, or diaphragm

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 446; UK Sample Size: 446

Total final enrolment
363

Key exclusion criteria

Current exclusion criteria as of 18/08/2017:
1. Patients with high grade dysplasia (squamous cell or adenocarcinoma)
2. Patients with T4b, or any stage with M1
3. Type 3 tumours of the oesophago-gastric junction that are scheduled for total gastrectomy
4. Patients with squamous cell cancer of the oesophagus who the MDT recommends or who individually elect to undergo definitive chemoradiotherapy
5. Evidence of previous complex thoracotomies or laparotomies that preclude a minimal access approach
6. Evidence of previous/concomitant malignancy that would interfere with this treatment protocol
7. Pregnancy
8. Patients participating in other trials that would interfere with the implementation of this protocol at a particular site

Previous exclusion criteria:
1. Patients with high grade dysplasia (squamous cell or adenocarcinoma)
2. Stage 4 disease
3. Type 3 tumours of the oesophago-gastric junction that are scheduled for total gastrectomy
4. Patients with squamous cell cancer of the oesophagus who the MDT recommends or who individually elect to undergo definitive chemoradiotherapy
5. Evidence of previous complex thoracotomies or laparotomies that preclude a minimal access approach
6. Evidence of previous/concomitant malignancy that would interfere with this treatment protocol
7. Pregnancy
8. Patients participating in other trials that would interfere with the implementation of this protocol at a particular site

Date of first enrolment
01/06/2016

Date of final enrolment
21/08/2019

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
Bristol Royal Infirmary
Upper Maudlin Street
Bristol
United Kingdom
BS2 8HW

Study participating centre
Derriford Hospital
Plymouth Hospitals NHS Foundation Trust
Derriford Road
Plymouth
United Kingdom
PL6 8DH

Study participating centre
Southampton General Hospital
University Hospital Southampton NHS Foundation Trust
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
Royal Infirmary of Edinburgh
NHS Lothian
GI Surgery
51 Little France Crescent
Edinburgh
United Kingdom
EH16 4SA

Study participating centre
Leicester Royal Infirmary
University Hospitals of Leicester NHS Trust#
Infirmary Square
Leicester
United Kingdom
LE1 5WW

Study participating centre
Royal Preston Hospital
Lancashire Teaching Hospitals NHS Foundation Trust
Chief Executive's Office
Sharoe Green Lane
Preston
United Kingdom
PR2 9HT

Study participating centre
Salford Royal
Salford Royal NHS Foundation Trust
Stott Lane
Salford
United Kingdom
M6 8HD

Study participating centre
Nottingham City Hospital
Upper GI Surgery
City Hospital
Hucknall Road
Nottingham
United Kingdom
NG5 1PB

Study participating centre
Royal United Hospitals Bath
Royal United Hospitals Bath NHS Foundation Trust
Combe Park
Bath
United Kingdom
BA1 3NG

Sponsor information

Organisation
University Hospitals Bristol NHS Foundation Trust

Sponsor details
Research & Innovation
Level 3 Education & Research Centre
Upper Maudlin Street
Bristol
England
United Kingdom
BS2 8AE

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04nm1cv11

Funder(s)

Funder type
Government

Funder Name
National Institute for Health 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 dissemination of the main trial results (clinical and cost-effectiveness) to surgeons and other clinicians through publication in a high profile journal which allows open access (to be published after the study has ended). This will be preceded by publication of the design of the definitive trial, allowing a fuller description of the methods, so enabling better understanding of the results. The study and results will also be disseminated at conferences attended by surgeons, such as the annual Association of Upper Gastro Intestinal Surgeons (AUGIS) meeting, and the NCRI Upper GI Clinical Studies Group Annual Trials Meeting.

Intention to publish date
01/04/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will not be made available for sharing until after publication of the main results of the research. Thereafter, anonymised individual patient data will be made available for secondary research, conditional on assurance from the secondary researcher that the proposed use of the data is compliant with the MRC Policy on Data Preservation and Sharing regarding scientific quality, ethical

requirements and value for money. A minimum requirement with respect to scientific quality will be a publicly available pre-specified protocol describing the purpose, methods and analysis of the secondary research, e.g. a protocol for a Cochrane systematic review. The second file containing patient identifiers would be made available for record linkage or a similar purpose, subject to confirmation that the secondary research protocol has been approved by a UK REC or other similar, approved ethics review body.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	quality assurance protocol	01/03/2019	30/03/2020	Yes	No
Protocol article	protocol	19/11/2019	27/10/2020	Yes	No
HRA research summary			28/06/2023	No	No
Statistical Analysis Plan	version 1	12/09/2019	02/01/2024	No	No
Statistical Analysis Plan	version 1	12/09/2019	02/01/2024	No	No
Plain English results			25/03/2024	No	Yes
Results article		02/03/2024	26/03/2024	Yes	No