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ROMIO feasibility: Randomised controlled trial of minimally invasive or open oesophagectomy

Submission date 21/02/2013	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 25/02/2013	**Overall study status** Completed	
Last Edited 07/06/2024	**Condition category** Cancer	

Plain English summary of protocol
http://www.cancerresearchuk.org/cancer-help/trials/a-study-comparing-different-types-surgery-treat-cancer-food-pipe-romio-pilot

Study website
https://bristol-trials-centre.bristol.ac.uk/details-of-studies/completed-studies/romio/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

HTA 10/50/65, 13859

Study information

Scientific Title
The ROMIO trial - Randomised Oesophagectomy: Minimally Invasive or Open, a feasibility study

Acronym
ROMIO

Study objectives
Current study hypothesis:
Study hypothesis
To compare, in patients with cancer of the oesophagus, the clinical and cost-effectiveness of minimally invasive and open surgical procedures in terms of recovery, health-related quality of life, cost and survival.

At present, we are conducting a feasibility study, during which the methodology and infrastructure for the main trial will be established. The core of this preliminary work will be an assessment of the feasibility of comparing surgical procedures for oesophagectomy in a pilot two-centre randomised trial. Specific objectives include:

1. To pilot the randomisation process and investigate reasons for any difficulties in recruitment so that these are tackled before the main trial.
2. To establish the proportion of potentially eligible patients who can be recruited to the trial, and so inform the number of centres required in the main trial.
3. To develop manuals for the different surgical procedures.
4. To develop a manual for the pathological processing.
5. To consider the appropriate statistical model for estimating treatment effectiveness whilst allowing for clustering in the data due to between surgeon variation.
6. To develop and evaluate an acceptable method of keeping patients blind to their allocation in the week after surgery.
7. To establish outcome measures for the main trial which are recognised as a comprehensive, valid and reliable assessment of oesophagectomy outcome.

Previous study hypothesis:
To compare, in patients with cancer of the oesophagus, the clinical and cost-effectiveness of minimally invasive and open surgical procedures in terms of recovery, health-related quality of life, cost and survival.

At present, we are conducting a feasibility study, during which the methodology and infrastructure for the main trial will be established. The core of this preliminary work will be an assessment of the feasibility of comparing surgical procedures for oesophagectomy in a pilot two-centre randomised trial. Specific objectives include:

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7. To establish outcome measures for the main trial which are recognised as a comprehensive, valid and reliable assessment of oesophagectomy outcome.

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/105065
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0011/81668/PRO-10-50-65.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South West - Frenchay, 17/07/2012, ref: 12/SW/0161

Study design
Randomised interventional 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 the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Upper Gastro-Intestinal Cancer/oesophageal cancer

Interventions
Lap-assisted oesophagectomy, This operation will consist of identical steps as described above, but access to the abdominal cavity will be achieved with four or five 10 or 5mm incisions and surgery performed laparoscopically. Placement of a feeding jejunostomy is at the surgeons discretion and may be performed laparoscopically or by extending a port site to a 8cm abdominal incision. The thoracic part of the operation will be performed as described above.

Open oesophagectomy, The operation consists of a two-phase oesophagectomy (abdomen and right chest) with a two-field lymphadenectomy (abdomen and thorax) and it will involve these key steps.

Abdominal phase:
The incision, (midline or subcostal) is at the surgeons discretion. Complete gastric mobilisation will be performed based on the right gastroepiploic and right gastric arteries. Pyloroplasty, pyloromyotomy or no drainage is at the surgeons discretion. Lymphadenectomies along the common hepatic artery.

Totally minimally invasive oesophagectomy (MIO): This will consist of performing the steps of the abdominal and chest phases of the operation as described above, but using laparoscopic and thoracoscopic techniques for each phase respectively. It may be a 3 phase minimally invasive operation. And the anastomosis is performed with a left cervical incision.

Follow Up Length: 6 month(s)

Intervention Type
Procedure/Surgery

Primary outcome measure
Fatigue (MFI-20); Timepoint(s): 2, 6, 42, 90, 185 days

Secondary outcome measures
1. Bang Blinding Index; Timepoint(s): 2, 6 days
2. HRQL; Timepoint(s): Pre-surgery, 6, 42, 90, 185 days
3. Length of hospital stay; Timepoint(s): day 42
4. Pain; Timepoint(s): Pre-surgery, 2, 3, 6 days
5. Procedural outcome measures; Timepoint(s): Lymph node count, positive resection margins, duration of operation, blood loss - day 42
6. Resource use; Timepoint(s): 6, 42, 90, 185 days
7. Spirometry (lung function); Timepoint(s): Pre-surgery, 3, 6 days
8. Surgical morbidity (Accordian & Clavien-Dindo classifications); Timepoint(s): 2, 3, 6 days
9. Survival time; Timepoint(s): 6 months

Overall study start date
31/01/2013

Completion date
21/10/2016

Eligibility

Key inclusion criteria
1. Male or female patients
2. Over 18 years of age
3. Oesophageal or oesophagogastric junctional adenocarcinoma, squamous cell cancer or high grade dysplasia
4. Endoscopic evidence before treatment of a tumour starting more than 5cm below cricopharyngeus
5. Endoscopic evidence before treatment of a tumour involving less than 4 centimetres of the gastric wall
6. Final tumour stage between high grade dysplasia and T3N1M0

7. Referred for primary oesophagectomy or referred for oesophagectomy after neoadjuvant treatment
8. Able to provide written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 72; UK Sample Size: 72

Total final enrolment
273

Key exclusion criteria
1. Stage 4 disease
2. Type 3 tumours of the oesophagogastric junction
3. Localised squamous cell cancer who elect to undergo definitive chemoradiotherapy
4. High grade dysplasia who elect to undergo radiofrequency ablation or endoscopic mucosal resection
5. Evidence of previous complex thoracotomies or laparotomies
6. Evidence of previous/concomitant malignancy that would interfere with the study protocol
7. Pregnancy
8. Participating randomised trials that may interfere with this protocol

Date of first enrolment
08/04/2013

Date of final enrolment
21/10/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Bristol
Senate House, Tyndall Avenue

Bristol
United Kingdom
BS8 1TH

Sponsor information

Organisation
University of Bristol (UK)

Sponsor details
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United Kingdom
BS8 1TH

Sponsor type
University/education

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

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available on request from chris.metcalfe@bristol.ac.uk 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	protocol	02/06/2014		Yes	No
Results article	results	01/06/2016		Yes	No
Protocol article	quality assurance protocol	01/03/2019	30/03/2020	Yes	No