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Minimally invasive oesophageal adenocarcinoma sentinel node biopsy 4.0

Submission date 05/04/2012	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 24/07/2012	**Overall study status** Completed	
Last Edited 06/07/2018	**Condition category** Cancer	

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/a-study-looking-finding-first-lymph-nodes-cancer-may-spread-people-having-surgery-cancer-food-pipe

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
11479

Study information

Scientific Title
A prospective, observational study evaluating a minimally invasive technique of identifying the sentinel lymph nodes in patients undergoing surgery for oesophageal adenocarcinoma

Study objectives
Oesophagectomy for cancer carries some of the highest morbidity and mortality risks of any elective surgical procedure. The incidence of oesophageal adenocarcinoma in the Western world is increasing dramatically and shows no signs of slowing down. Endoscopic surveillance of Barrett s oesophagus is also anticipated to increase numbers of patients with high-grade dysplasia of the oesophagus who may require resectional surgery. Studies indicate that the routinely performed extended lymphadenectomy contributes significantly to the risks of surgery. However, determining which patients do not require a radical lymphadenectomy is limited by the relatively low sensitivity and specificity of pre-operative staging investigations. Minimally invasive techniques such as laparoscopic gastric mobilisation and thoracoscopic oesophageal mobilisation have been developed to reduce surgical trauma. These techniques need to be equally as radical in terms of the lymphadenectomy although this can be difficult in some cases. The sentinel lymph node (SLN) concept is that if the first draining lymph node in proximity to a cancer is clear of cancer cells then no other nodes should be involved.

A minimally invasive resection technique coupled to a sensitive minimally invasive SLN assessment could potentially reduce surgical morbidity by identifying patients who could have less extensive surgery without compromising oncological clearance. The SLN status might be the determining factor in deciding whether a patient is indeed suitable for minimally invasive surgery. Furthermore, the technique could also be applied to tailor surgery for those patients having open resections and determine the lymph node status for patients having endoscopic mucosal and submucosal resections for very superficial adenocarcinoma.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North EastCounty Durham & Tees Valley, First MREC 04/10/2011, ref: 11/NE /0262

Study design
Observational trial

Primary study design
Observational

Secondary study design
Other

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

Interventions
Laparoscopic gamma probe identification of abdominal sentinel lymph nodes following endoscopic peritumoural technetium injection.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Sentinel lymph node identification
2. Numbers of patients in whom the abdominal sentinel lymph node is identified after study completion

Secondary outcome measures
No secondary outcome measures

Overall study start date
20/02/2012

Completion date
01/10/2013

Eligibility

Key inclusion criteria
1. All patients with potentially curable lower third oesophageal adenocarcinoma or oesophagogastric junction adenocarcinoma planned to undergo curative twostage oesophagectomy
2. Male and female participants

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants

Planned Sample Size: 40; UK Sample Size: 40

Key exclusion criteria
1. Incurable disease
2. Not suitable for laparoscopy

Date of first enrolment
20/02/2012

Date of final enrolment
01/10/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Victoria Infirmary
Newcastle upon Tyne
United Kingdom
NE1 4LP

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

Sponsor details
Royal Victoria Infirmary
Leazes Wing
Queen Victoria Road
Newcastle Upon Tyne
England
United Kingdom
NE1 4LP

Sponsor type
Hospital/treatment centre

Website
http://www.newcastle-hospitals.org.uk/

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
University/education

Funder Name
Bupa Foundation

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Funder Name
Royal College of Surgeons of England

Alternative Name(s)
RCS

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

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

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results	results	16/09/2016		No	No