ISRCTN71969151 https://doi.org/10.1186/ISRCTN71969151

# Minimally invasive oesophageal adenocarcinoma sentinel node biopsy 4.0

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

**Protocol serial number**
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

## Primary study design
Observational

## Study design
Observational trial

## Study type(s)
Treatment

## 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(s)
1. Sentinel lymph node identification
2. Numbers of patients in whom the abdominal sentinel lymph node is identified after study completion

### Key secondary outcome(s)
No secondary outcome measures

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
All

### 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
United Kingdom

England

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

# Sponsor information

**Organisation**
Newcastle upon Tyne Hospitals NHS Foundation Trust (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 England, RCS ENG, The Royal College of Surgeons of England, RCS

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
Universities (academic only)

**Location**
United Kingdom

# Results and Publications

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

## Study outputs

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