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# The role of Thalidomide in Reversing Cachexia in Patients with Oesophageal Cancer

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| **Submission date**<br>29/09/2006 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>29/09/2006 | **Overall study status**<br>Completed | |
| **Last Edited**<br>07/09/2012 | **Condition category**<br>Cancer | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
N0077075338

# Study information

### Scientific Title

### Study objectives
Does Thalidomide reverse the metabolic effects of cachexia in oesophageal cancer patients?

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Not provided at time of registration

### Study design
Randomised controlled trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Not specified

### Study type(s)
Not Specified

### 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
Cancer: Oesophageal

### Interventions
Thalidomide will be prescribed strictly in accordance with the regulations laid down by S.T.E.P.S. (System for Thalidomide Education & Prescribing Safety). Patients will be established on an isocaloric diet over a 10 day period. The total daily energy content of the diet will be estimated from Harris-Benedict equation for REE with a standard increment above the baseline to allow for activity. Thalidomide will be administered at a dose of 200 mg/day for 14 days. After 14 days, the subjects will continue to remain on the isocaloric diet for another 2 weeks. Body weight and composition will be measured by DEXA scanning at the start of the study, after thalidomide treatment and at the end of the study. REE will be measured by indirect calorimetry using ventilated hood apparatus. Measurements will be made both during fasting state and also post meals at the same intervals as body composition assessments. Urine will be collected for estimation of 24 hr urea nitrogen excretion, creatinine, uric acid, protein at weekly intervals. Routine biochemistry, blood counts, lipids, TFT, cortisol, catecholamines, free fatty acids, non-esterified fatty acids, insulin and lactate. Each patient will be seen for a detailed history and

thorough clinical examination at weekly intervals. In addition, the following clinical parameters will be noted; quality of life questionnaire (Karnofsky Index), nutritional status, and a detailed neurological examination will be conducted to look for evidence of neurotoxicity. Sensory nerve action potential amplitudes of median, radial and sural nerve will be measured at baseline (2 readings) and again if indicated by development of neurotoxicity. Development of any signs of neurotoxicity or parasthesia will result in immediate cessation of therapy and objective assessment by nerve conduction study.

### Intervention Type
Drug

### Phase
Not Specified

### Drug/device/biological/vaccine name(s)
Thalidomide

### Primary outcome measure
Reduction in metabolic rate, weight gain and improvement in quality of life.

### Secondary outcome measures
Not provided at time of registration

### Overall study start date
01/01/2003

### Completion date
30/06/2006

## Eligibility

### Key inclusion criteria
12 oesophageal cancer patients will be recruited from the endoscopy database. Inclusion criteria:
1. Patients with non obstructing and inoperable oesophageal cancer
2. Able to swallow a semi solid diet (Dysphagia score <3)

### Participant type(s)
Patient

### Age group
Not Specified

### Sex
Not Specified

### Target number of participants
12

### Key exclusion criteria

1. Pre menopausal women
2. Patients receiving any adjuvant chemo or radiotherapy
3. Patients with oesophageal obstruction
4. Patients with established neuropathy
5. Patients requiring frequent laser ablation sessions
6. Patients unable to take a constant calorific intake
7. Increased debility

### Date of first enrolment
01/01/2003

### Date of final enrolment
30/06/2006

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
**Derby Hospitals NHS Foundation Trust**
Derby
United Kingdom
DE22 3NE

## Sponsor information

### Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

### Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

### Sponsor type
Government

### Website

http://www.dh.gov.uk/Home/fs/en

# Funder(s)

### Funder type
Government

### Funder Name
Derby Hospitals NHS Foundation Trust (UK), NHS R&D Support Funding

# 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? |
|---|---|---|---|---|---|
| Results article | results | 01/02/2006 | | Yes | No |