

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

<b>Submission date</b> 28/04/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 06/06/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 22/08/2012	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

**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**  
SDAH/2000/009

## Study information

## **Scientific Title**

### **Study objectives**

Thalidomide increases weight (mainly lean body mass). This effect is mediated by suppression of tumour necrosis factor.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved by the Derbyshire Research Ethics Committee on 13/12/2000, reference number: 0003 /150

### **Study design**

Double-blind placebo controlled trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Not specified

### **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**

Oesophageal cancer

### **Interventions**

Thalidomide versus placebo

### **Intervention Type**

Drug

### **Phase**

Not Specified

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

Thalidomide

### **Primary outcome measure**

Change in lean body mass

**Secondary outcome measures**

1. Change in resting energy expenditure
2. Change in total body weight

**Overall study start date**

10/12/2002

**Completion date**

16/06/2006

**Eligibility****Key inclusion criteria**

Adults with non-obstructing and inoperable oesophageal cancer (dysphagia score <3, able to swallow a semi-solid diet)

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

34

**Key exclusion criteria**

1. Pre-menopausal women
2. Patients receiving any adjuvant chemotherapy or radiotherapy
3. Patients with oesophageal obstruction
4. Those with established neuropathy
5. Patients requiring frequent laser ablation sessions
6. Those unable to maintain an adequate caloric intake
7. Increased debility

**Date of first enrolment**

10/12/2002

**Date of final enrolment**

16/06/2006

**Locations****Countries of recruitment**

England

United Kingdom

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

## **Sponsor information**

**Organisation**  
Derby Hospitals NHS Foundation Trust (UK)

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**Sponsor type**  
Hospital/treatment centre

## **Funder(s)**

**Funder type**  
Charity

**Funder Name**  
The research was funded in part by the MAGIC appeal (registered charity number: 1061812) and in part by matched funds from Derby Hospitals Research and Development grant scheme.

## **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?
<a href="#">Results article</a>	results	01/09/2011		Yes	No