

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

Submission date 28/04/2006	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 06/06/2006	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 22/08/2012	Condition category Cancer	☐ 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

Protocol serial number
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

Primary study design

Interventional

Study design

Double-blind placebo controlled trial

Study type(s)

Treatment

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(s)

Change in lean body mass

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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**

United Kingdom

England

Study participating centre

Derby Hospitals NHS Foundation Trust

Derby

United Kingdom

DE22 3NE

Sponsor information**Organisation**

Derby Hospitals NHS Foundation Trust (UK)

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

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	01/09/2011		Yes	No