ISRCTN23944748 https://doi.org/10.1186/ISRCTN23944748

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

Submission date	Recruitment status	[_] Prospectively registered
28/04/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
06/06/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
22/08/2012	Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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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)

Sponsor details
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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?
Results article	results	01/09/2011		Yes	No