

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

Submission date 29/09/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 29/09/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 07/09/2012	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Emilie Wilkes

Contact details
Derby Hospitals NHS Foundation Trust
Department of Gastroenterology
Derby City General Hospital
Uttoxeter Road
Derby
United Kingdom
DE22 3NE

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

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