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

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

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
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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Not Specified

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(s)
Reduction in metabolic rate, weight gain and improvement in quality of life.

Key secondary outcome(s)
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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
United Kingdom

England

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

Funder(s)

Funder type
Government

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

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	01/02/2006		Yes	No