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The use of thalidomide as a treatment for cancer cachexia

Submission date	Recruitment status	[ ] Prospectively registered
23/09/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
23/11/2005	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
16/03/2017	Cancer	[ ] Record updated in last year

Plain English summary of protocol
http://www.cancerhelp.org.uk/trials/a-trial-looking-at-thalidomide-for-cancer-patients-with-weight-loss.

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
220105v1

Study information

Scientific Title
The use of thalidomide as a treatment for cancer cachexia

Study objectives
Thalidomide can attenuate or reverse both the total weight loss and loss of lean body mass in the cachexia associated with upper gastrointestinal adenocarcinomas.

On 15/02/2011 the anticipated end date for this trial was changed from 03/10/2007 to 28/02/2011.

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

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Cachexia associated with upper gastrointestinal adenocarcinoma

Interventions
Thalidomide or placebo

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Thalidomide

Primary outcome(s)
To evaluate the ability of thalidomide, as compared with placebo, to attenuate loss of weight in patients with incurable upper gastrointestinal carcinomas

Key secondary outcome(s))
1. To assess any impact on functional or overall quality of life
2. To calculate any change in overall survival
3. To calculate any change in lean muscle mass
4. To calculate any change in grip strength
5. To obtain serum and urinary profiles of factors previously implicated in the development of cachexia for both the control and treated group
6. To document the safety and tolerability of thalidomide in patients with incurable upper gastrointestinal adenocarcinomas

Completion date
28/02/2011

Eligibility

Key inclusion criteria
1. Have a histological or cytological diagnosis of upper gastrointestinal (oesophagus, stomach, small bowel, ampulla or pancreas) adenocarcinoma
2. Have no curative options available which are acceptable to the patient
3. Have lost 5% total of pre-morbid body weight or be actively losing at least 1 kg per month
4. Weight loss may be self-reported or obtained from previous documentation
5. If a patient is using megesterol acetate (Megace, Megestrol) or eicosapentaenoic acid (Maxepa, Omacor, Prosure) and has been on a stable dose for at least 1 month but losing weight at the stated rate despite this they may be included. They will be asked to continue on this same dose for the course of the study.
6. Those using corticosteroids, non-steroidal anti-inflammatory drugs and other nutritional supplements or complementary therapies will not be restricted, the doses used will be recorded at each clinic visit
7. Have a predicted survival of at least 8 weeks
8. Aged over 18 years at the time of entry into the trial
9. Able to understand the information given and to give written informed consent
10. Able to take oral medications
11. Agree to the conditions of use of thalidomide as enumerated
12. Women who have not had their ovaries or uterus removed or who have been post-menopausal for at least 2 years, must have a negative urinary pregnancy test and negative pregnancy tests repeated on a monthly basis until 1 month after completion of the trial

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Unable to provide informed consent
2. Involved in any other trial during the study period
3. Received chemotherapy or radiotherapy within the previous 4 weeks
4. Expected to receive chemotherapy or radiotherapy in the following 6 months
5. Using varying doses of megesterol acetate or eicosapentaenoic acid
6. Clinically detectable ascites or oedema
7. Unable to take oral medication

8. Pregnant or breastfeeding
9. Unable or considered unlikely to avoid pregnancy
10. Evidence of peripheral neuropathy, severe constipation, vertigo or vestibular disease
11. Previous adverse reaction to thalidomide
12. Any condition judged by the investigator to make the patient unsuitable for inclusion into the study due to interference with absorption of the drug or the overall interpretation of the data

Date of first enrolment
03/10/2005

Date of final enrolment
28/02/2011

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Gastroenterology Dept
Portsmouth
United Kingdom
PO6 3LY

Sponsor information

Organisation
Portsmouth Hospitals Trust (UK)

ROR
https://ror.org/009fk3b63

Funder(s)

Funder type
Charity

Funder Name
The Moulton Charitable Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration