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 | | Individual participant data |
| 16/03/2017 | | [] 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

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

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

Secondary outcome measures

- 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

Overall study start date

03/10/2005

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 postmenopausal 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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

180

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

England

United Kingdom

Study participating centre Gastroenterology Dept

Portsmouth United Kingdom PO6 3LY

Sponsor information

Organisation

Portsmouth Hospitals Trust (UK)

Sponsor details

Kate Greenwood
Gloucester House
Queen Alexandra Hospital
Southwick Hill Road
Cosham
Portsmouth
England
United Kingdom
PO6 3LY

Sponsor type

Hospital/treatment centre

ROR

https://ror.org/009fk3b63

Funder(s)

Funder type

Charity

Funder Name

The Moulton Charitable Trust (UK)

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