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Oral Treosulfan In Ewing's Sarcoma

Submission date 28/11/2008	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 17/12/2008	**Overall study status** Completed	
Last Edited 25/01/2022	**Condition category** Cancer	

Plain English summary of protocol
http://www.cancerhelp.org.uk/trials/a-trial-looking-treosulfan-treat-Ewings-sarcoma-come-back-after-treatment-OTIS

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
08/0230

Study information

Scientific Title
A phase II study to determine the efficacy and safety of conventional dose oral treosulfan in patients with advanced pre-treated Ewing's sarcoma

Acronym
OTIS

Study objectives
This is a non-randomised phase II study which aims to explore the efficacy and toxicity of oral treosulfan in patients with advanced, pre-treated Ewing's sarcoma. If conventional dose oral treosulfan is demonstrated to be active in patients with advanced Ewing's sarcoma, it is proposed that this study should be followed by a phase III prospective randomised controlled trial comparing oral etoposide (the traditional active palliation agent in solid tumours) with oral treosulfan.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Derby 1 (Trent) and Derby 2 Research Ethics Committees, 07/08/2009, ref: 09H0405-29

Primary study design
Interventional

Study design
Non-randomised phase II study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Ewing's sarcoma

Interventions
Non-randomised phase II study of oral treosulfan in advanced pre-treated Ewing's sarcoma. Treosulfan 1 g/m^2 will be administered in three divided doses, daily over 7 days and repeated every 28 days, until disease progression, unacceptable toxicity or patient refusal.

Intervention Type
Drug

Phase
Phase II

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

Primary outcome(s)
Current primary outcomes measure as of 29/11/2011:
Objective response rate achieved: tumour response will be measured as defined by the RECIST guidelines.

Previous primary outcome measure:
Objective response rate achieved: tumour response will be measured as defined by the RECIST guidelines. Following analysis of data for initial 15 patients, if the measured success is less than or equal to 10% then the study will be stopped. Otherwise, the study will close once a total of 25 eligible patients have been enrolled.

Key secondary outcome(s)
Current secondary outcome measures as of 29/11/2011:
1. Event-free survival
2. Overall survival
3. Toxicity : if there is more than one toxic death, or more than two unexpected treatment related serious adverse events occurring in two separate individuals, an Independent Data Monitoring Committee meeting will take place and advice sought regarding continuing the trial
4. Duration of response
5. Time to progression/relapse

Previous secondary outcome measures:
1. Toxicity: if there is more than one toxic death, or more than two unexpected serious adverse events occurring in two separate individuals, the chief/co-investigators will consider stopping the trial
2. Duration of response
3. Time to progression
4. Correlation of deoxyribonucleic acid (DNA) cross-linking and retention with response and toxicity

Completion date
11/09/2012

Eligibility

Key inclusion criteria
Current inclusion criteria as of 29/11/2011:
1. Age less than 50 years, either sex
2. Histologically proven Ewing's sarcoma/peripheral neuroectodermal tumour
3. Patients with advanced, refractory disease who have failed at least one course of conventional chemotherapy and for whom no curative option exists
4. Measurable disease, defined by Response Evaluation Criteria in Solid Tumors (RECIST)
5. Evidence of disease progression within the preceding 8 weeks
6. Neutrophils greater than or equal to 1.5 x 10^9/l and platelet count greater than or equal to 100 x 10^9/l
7. Creatinine less than or equal to 1.5 x upper limit of normal (ULN)
8. Serum bilirubin and aspartate aminotransferase (AST)/alanine aminotransferase (ALT) less than or equal to 1.5 x ULN
9. Performance status 0-2 (patients 16 years or older) or Lansky Performance Status greater than 30 (patients under 16 years). (n.b. patients with WHO performance status 3 due to spinal disease will be eligible provided they are otherwise medically well)
10. Patient able to comply with protocol treatment (swallow capsules) and follow up
11. Life expectancy of three months or greater
12. Written informed consent of patient or parent/legal guardian

Previous inclusion criteria:
9. World Health Organization (WHO) performance status greater than 3 (patients greater than 16 years); or Lansky Performance Status greater than 30

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Other

Sex
All

Total final enrolment
21

Key exclusion criteria
1. Newly diagnosed, or resectable Ewing's sarcoma
2. Pregnant/lactating women, or women of childbearing potential unless using effective contraception
3. Concurrent treatment with any other anti-cancer therapy, except palliative radiotherapy to non-target lesions
4. Concurrent treatment with other experimental drugs
5. Concurrent treatment with growth factors

Date of first enrolment
02/02/2010

Date of final enrolment
11/09/2012

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University College London
London
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Sponsor information

Organisation
University College London (UK)

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Charity

Funder Name
Adam Dealey Foundation (UK)

Funder Name
Medac International (UK)

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

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	01/01/2015		Yes	No
Plain English results		28/05/2015	25/01/2022	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes