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Gemcitabine and Docetaxel versus Doxorubicin as first line treatment in previously untreated advanced unresectable or metastatic soft tissue Sarcomas

Submission date
29/07/2009

Recruitment status
No longer recruiting

Registration date
11/09/2009

Overall study status
Completed

Last Edited
24/01/2022

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
http://www.cancerhelp.org.uk/trials/a-trial-comparing-gemcitabine-docetaxel-with-doxorubicin-soft-tissue-sarcomas-geddis

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
UCL 09/0060

Study information

Scientific Title
A prospective randomised controlled phase III trial of gemcitabine and docetaxel compared with doxorubicin as first line treatment in previously untreated advanced unresectable or metastatic soft tissue sarcomas

Acronym
GeDDiS

Study objectives
The proposed study aims to determine whether the combination of gemcitabine and docetaxel is associated with an improved clinical outcome compared with single agent doxorubicin.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Central London REC 2, Royal Free Hospital, London, 11/08/2010, ref: 10/H0713/54

Study design
Randomised controlled phase III multi-national trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Soft tissue sarcomas

Interventions

Standard arm: doxorubicin 75 mg/m^2 day 1 every three weeks for up to 6 cycles.
Experimental arm: gemcitabine 675 mg/m^2 days 1 and 8, docetaxel 75 mg/m^2 day 8 every three weeks for up to 6 cycles with granulocyte-colony stimulating factor (GCSF) support days 8 - 15.

Both arms consist of six, three weekly cycles, a total of 18 weeks of treatment. Following treatment, patients will be followed up two monthly with clinical evaluation and scanning until disease progression, or death.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Gemcitabine, docetaxel, doxorubicin

Primary outcome measure
Progression-free survival, assessed using the RECIST Criteria every six weeks (after each set of two cycles); following treatment assessment will be 2-monthly.

Secondary outcome measures
1. Overall survival, time to progression and objective response rate assessed using the RECIST Criteria every six weeks (after each set of two cycles); following treatment assessment will be 2-monthly
2. Toxicity, continuously assessed and recorded using the NCI Common Terminology Criteria for Adverse Events v4.0
3. Quality of life, measured using the EORTC QLQ C30 for patients aged 16 years and greater and the PEDQOL questionnaire for patients aged less than 15 years. The EQ5D will also be used for health economic evaluation. Measured at baseline, prior to cycle 3 (6 weeks), prior to cycle 6 (15 weeks) and six weeks after the completion of treatment.

Overall study start date
01/01/2010

Completion date
01/01/2013

Eligibility

Key inclusion criteria
1. Locally advanced or metastatic soft tissue sarcoma, incurable by surgery or radiotherapy
2. Evidence of disease progression in the 6 weeks prior to trial entry
3. No prior chemotherapy regimen for advanced or metastatic disease; (neo)adjuvant therapy is allowed
4. World Health Organization (WHO) performance status 0 - 2
5. Aged greater or equal to 13 years, either sex
6. Histologically confirmed soft tissue sarcoma excluding: alveolar soft part sarcoma, gastrointestinal stromal tumour, Ewing's sarcoma family of tumours, rhabdomyosarcoma

7. Desmoplastic small round cell tumour, extra-skeletal myxoid chondrosarcoma
8. Histological material available for central review
9. Measurable disease evaluable by Response Evaluation Criteria In Solid Tumours (RECIST) criteria
10. Life expectancy of at least 3 months
11. Adequate organ function:
11.1. Neutrophils greater than 1.5
11.2. Platelets greater than 100
11.3. Bilirubin less than or equal to 1.5 x upper limit of normal (ULN)
11.4. Aspartate aminotransferase (AST) less than or equal to 3 x ULN
11.5. Serum creatinine less than or equal to 1.5 x ULN; measured creatinine clearance greater or equal to 50 ml/min
12. Ejection fraction as assessed by multiple-gated acquisition scan (MUGA) or echocardiogram (ECHO) greater than or equal to 50%

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
250

Key exclusion criteria
1. Known active central nervous system (CNS) metastases
2. Grade 3 or 4 peripheral neuropathy
3. Pregnancy or lactating
4. Active uncontrolled infection including known a history of acquired immune deficiency syndrome (AIDS)
5. Patients with previous non-sarcomatous malignancy should not have detectable disease and must not be on active treatment for the disease
6. Any serious and/or unstable pre-existing medical, psychiatric or other condition that could interfere with patient safety or obtaining informed consent

Date of first enrolment
01/01/2010

Date of final enrolment
01/01/2013

Locations

Countries of recruitment
Australia

England

Ireland

United Kingdom

Study participating centre
UCL Hospital NHS Trust
London
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NW1 2PG

Sponsor information

Organisation
University College London (UCL) (UK)

Sponsor details
Joint UCLH and UCL Biomedical Research Unit
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Sponsor type
University/education

Website
http://www.ucl.ac.uk/

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (CRUK) (UK)

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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	01/10/2017		Yes	No
Plain English results			24/01/2022	No	Yes
HRA research summary			28/06/2023	No	No