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	[X] Prospectively registered [] Protocol
Registration date 11/09/2009	Overall study status Completed	
Last Edited 24/01/2022	Condition category Cancer	[] 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

Contact name

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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 United Kingdom NW1 2PG

Sponsor information

Organisation

University College London (UCL) (UK)

Sponsor details

Joint UCLH and UCL Biomedical Research Unit 1st Floor Maple House Ground Floor, Rosenheim Wing 25 Grafton Way London England United Kingdom WC1E 5DB

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 results	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/10/2017		Yes	No
Plain English results			24/01/2022	No	Yes
HRA research summary			28/06/2023	No	No