

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 11/09/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 24/01/2022	Condition category Cancer	<input type="checkbox"/> 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

Protocol serial number

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

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Soft tissue sarcomas

Interventions

Standard arm: doxorubicin 75 mg/m² day 1 every three weeks for up to 6 cycles.

Experimental arm: gemcitabine 675 mg/m² days 1 and 8, docetaxel 75 mg/m² 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(s)

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

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Mixed

Sex

All

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**

United Kingdom

England

Australia

Ireland

Study participating centre

UCL Hospital NHS Trust

London

United Kingdom

NW1 2PG

Sponsor information**Organisation**

University College London (UCL) (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, Cancer Research UK (CRUK), CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Study outputs

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