

A randomised trial of chemotherapy with or without granulocyte colony-stimulating factor (G-CSF) in operable osteosarcoma

Submission date 28/02/2001	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 28/02/2001	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 11/05/2022	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

http://www.ctu.mrc.ac.uk/research_areas/study_details.aspx?s=107

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

BO06

Study information

Scientific Title

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Study objectives

To compare two regimens of chemotherapy using Doxorubicin and Cisplatin in operable osteosarcoma: one involving chemotherapy at three weekly intervals with surgery after two courses, the other, chemotherapy at two weekly intervals plus G-CSF with surgery after three courses.

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

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Osteosarcoma

Interventions

Two regimens of chemotherapy:

1. The first is Doxorubicin and Cisplatin at three weekly intervals with surgery after two courses /chemotherapy.
2. The second is Doxorubicin and Cisplatin at two weekly intervals plus G-CSF with surgery after three courses.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Doxorubicin and Cisplatin

Primary outcome(s)

1. Survival time
2. Response rate
3. Morbidity
4. Response duration

Key secondary outcome(s)

Not provided at time of registration

Completion date

30/09/2002

Eligibility

Key inclusion criteria

1. Untreated non-metastatic disease
2. Age less than or equal to 40 years
3. Neutrophils ≥ 1.5 times $10^9/l$ and platelets ≥ 100 times $10^9/l$
4. Glomerular Filtration Rate (GFR) ≥ 60 ml/min/1.73 m²
5. Serum bilirubin \leq micromoles/L
6. Normal cardiac function
7. Informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Not Specified

Total final enrolment

497

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/07/1993

Date of final enrolment

30/09/2002

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

MRC Clinical Trials Unit

London

United Kingdom

NW1 2DA

Sponsor information

Organisation

Medical Research Council (MRC) (UK)

Funder(s)

Funder type

Research council

Funder Name

Medical Research Council (MRC) (UK)

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

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	17/01/2007		Yes	No
Other publications	retrospective analysis	01/05/2019	13/02/2020	Yes	No
Other publications	retrospective analysis	30/05/2019	28/04/2020	Yes	No
Other publications	retrospective analysis	16/12/2021	20/12/2021	Yes	No

Other publications	retrospective reanalysis	10/05/2022	11/05/2022	Yes	No
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