

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

<b>Submission date</b> 28/02/2001	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 28/02/2001	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 11/05/2022	<b>Condition category</b> 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](http://www.ctu.mrc.ac.uk/research_areas/study_details.aspx?s=107)

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

BO06

# Study information

## Scientific Title

-

## 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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

## 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 measure**

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

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/07/1993

**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  $\geq 1.5$  times  $10^9/l$  and platelets  $\geq 100$  times  $10^9/l$
4. Glomerular Filtration Rate (GFR)  $\geq 60$  ml/min/ $1.73$  m<sup>2</sup>
5. Serum bilirubin  $\leq$  micromoles/L
6. Normal cardiac function
7. Informed consent

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Not Specified

**Target number of participants**

500

**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**

England

United Kingdom

**Study participating centre**

**MRC Clinical Trials Unit**

London

United Kingdom

NW1 2DA

## Sponsor information

**Organisation**

Medical Research Council (MRC) (UK)

**Sponsor details**

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**Sponsor type**

Research council

**Website**

<http://www.mrc.ac.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, MRC

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**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?
<a href="#">Results article</a>	results	17/01/2007		Yes	No
<a href="#">Other publications</a>	retrospective analysis	01/05/2019	13/02/2020	Yes	No
<a href="#">Other publications</a>	retrospective analysis	30/05/2019	28/04/2020	Yes	No
<a href="#">Other publications</a>	retrospective analysis	16/12/2021	20/12/2021	Yes	No
<a href="#">Other publications</a>	retrospective reanalysis	10/05/2022	11/05/2022	Yes	No