

# A Randomised Trial of Two Chemotherapy Regimens in the Treatment of Operable Osteosarcoma (Doxorubicin-Cisplatin versus Methotrexate-Vincristine-Doxorubicin plus Doxorubicin-Cisplatin plus Bleomycin-Cyclophosphamide-Dactinomycin)

<b>Submission date</b> 19/08/2002	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 19/08/2002	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 12/04/2012	<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=104](http://www.ctu.mrc.ac.uk/research_areas/study_details.aspx?s=104)

## Contact information

### Type(s)

Scientific

### Contact name

Dr Barbara Uscinska

### Contact details

MRC Clinical Trials Unit  
222 Euston Road  
London  
United Kingdom  
NW1 2DA  
+44 (0) 20 7670 4723  
[register@ctu.mrc.ac.uk](mailto:register@ctu.mrc.ac.uk)

## Additional identifiers

### Protocol serial number

BO03/EORTC 80861

# Study information

## Scientific Title

## Study objectives

To assess two protocols of chemotherapy in operable osteosarcoma.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Not provided at time of registration.

## Primary study design

Interventional

## Study design

Randomised controlled trial

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Bone cancer

## Interventions

Patients are randomised to one of two treatment groups:

1. Group A: Two drug chemotherapy, cisplatin and adriamycin (doxorubicin) repeated every 3 weeks for three cycles. Surgery is recommended 3 weeks following the completion of chemotherapy. Three further courses of chemotherapy to be given postoperatively.

2. Group B: Multi-drug chemotherapy with vincristine, high-dose methotrexate, adriamycin, bleomycin, cisplatin, cyclophosphamide and dactinomycin. The duration of chemotherapy is 44 weeks. Surgery is recommended for week 7 of chemotherapy.

## Regimen:

Group A: Cisplatin 100 mg/m<sup>2</sup> 24 h infusion and adriamycin 25 mg/m<sup>2</sup> days 1, 2, 3 at weeks 0, 3, 6, 9, 11, 14. Surgery week 9.

Group B: High dose methotrexate (M) 8 g/m<sup>2</sup> or 12 g/m<sup>2</sup> (age 12 or less) 6 h infusion day 1; Vincristine (V) 1.5 mg/m<sup>2</sup> (max 2 mg) iv bolus day 1; adriamycin (A1) 25 mg/m<sup>2</sup> iv bolus, days 1-3; (A2) 30 mg/m<sup>2</sup>, days 1, 2; bleomycin (B) 15 mg/m<sup>2</sup>; cyclophosphamide (C) 600 mg/m<sup>2</sup>, dactinomycin (D) 600 mg/m<sup>2</sup>; cisplatin (P) 120 mg/m<sup>2</sup>; VM weeks 0, 1, 5, 6, 12, 13, 17, 18; A1 weeks 2, 14; A2+P weeks 20, 23, 29, 32, 38, 41; BCD weeks 9, 26, 35. Surgery week 7.

## Intervention Type

Drug

## Phase

Not Specified

**Drug/device/biological/vaccine name(s)**

Doxorubicin-Cisplatin versus Methotrexate-Vincristine-Doxorubicin plus Doxorubicin-Cisplatin plus Bleomycin-Cyclophosphamid-Dactinomycin

**Primary outcome(s)**

Overall survival, relapse-free survival, response to pre-operative chemotherapy

**Key secondary outcome(s)**

Not provided at time of registration.

**Completion date**

01/03/1993

## Eligibility

**Key inclusion criteria**

1. Aged <40 years
2. Biopsy proven osteosarcoma
3. Non-metastatic, untreated osteosarcoma of the long bones of an extremity
4. Normal cardiac, renal, hepatic, hematologic and pulmonary function prior to entry
5. Patients with parosteal, periosteal, pagetoid and post irradiation sarcoma or who have an inoperable tumour are excluded
6. No previous chemotherapy
7. No previous radiotherapy to the primary tumour
8. No medical contraindications to treatment

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Key exclusion criteria**

Not provided at time of registration.

**Date of first enrolment**

01/06/1986

**Date of final enrolment**

01/03/1993

## 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

Other

### Funder Name

Medical Research Council, European Organisation for Research and Treatment of Cancer (EORTC)

## Results and Publications

### Individual participant data (IPD) sharing plan

### 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	27/09/1997		Yes	No