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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)

Submission date 19/08/2002	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/08/2002	**Overall study status** Completed	
Last Edited 12/04/2012	**Condition category** Cancer	

Plain English summary of protocol
http://www.ctu.mrc.ac.uk/research_areas/study_details.aspx?s=104

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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/m2 24 h infusion and adriamycin 25 mg/m2 days 1, 2, 3 at weeks 0, 3, 6, 9,11,14. Surgery week 9.
Group B: High dose methotrexate (M) 8 g/m2 or 12 g/m2 (age 12 or less) 6 h infusion day 1; Vincristine (V) 1.5 mg/m2 (max 2 mg) iv bolus day 1; adriamycin (A1) 25 mg/m2 iv bolus, days 1-3; (A2) 30 mg/m2, days 1, 2; bleomycin (B) 15 mg/m2; cyclophosphamide (C) 600 mg/m2, dactinomycin (D) 600 mg/m2; cisplatin (P) 120 mg/m2; 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 measure
Overall survival, relapse-free survival, response to pre-operative chemotherapy

Secondary outcome measures
Not provided at time of registration.

Overall study start date
01/06/1986

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

Age group
Adult

Sex
Both

Target number of participants
400

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
England

United Kingdom

Study participating centre
MRC Clinical Trials Unit
London
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Sponsor information

Organisation
Medical Research Council (MRC) (UK)

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Sponsor type

Research council

Website
http://www.mrc.ac.uk

Funder(s)

Funder type
Other

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

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Results article	results	27/09/1997		Yes	No