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

Plain English summary of protocol

http://www.ctu.mrc.ac.uk/research_areas/study_details.aspx?s=104

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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.

Study design

Randomised controlled trial

Primary study design

Interventional

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/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

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

Αll

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?
Results article	results	27/09/1997		Yes	No