ISRCTN86294690 https://doi.org/10.1186/ISRCTN86294690

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

Registration date
28/02/2001

Overall study status
Completed

Last Edited
11/05/2022

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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Additional identifiers

Protocol serial number
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

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 m^2
5. Serum bilirubin ≤ 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, 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