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Italian Sarcoma Group: non-metastatic OsteoSarcoma 1

Submission date	Recruitment status	[_] Prospectively registered
15/02/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/03/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
01/09/2021	Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Italian Sarcoma Group: non-metastatic OsteoSarcoma 1

Acronym
ISG/OS-1

Study objectives
Osteosarcoma (OS) is a high-grade malignant spindle cell tumor arising within the bone and histologically characterized by the production of tumor osteoid or an immature bone directly from the malignant spindle cell stroma. It is the most frequent type of malignant bone tumor in children and adolescents. At present, the most effective drugs used are methotrexate (MTX), doxorubicin (DOX), ifosfamide (IFO), cisplatinum (CDP).

Hypothesis:
A chemotherapy treatment based on ifosfamide delivered only in the post-operative phase and in patients that are histologically poor responders to primary treatment with methotrexate (MTX), cisplatinum (CDP), doxorubicin (DOX) is equivalent to a treatment using ifosfamide added to MTX, CDP and DOX since the primary phase in all patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Orthopaedic Institute Rizzoli (Istituti Ortopedici Rizzoli) on the 31st January 2001 (ref: 19/CE/US).

Study design
Randomised controlled trial, open label

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Patients are randomised to receive a treatment with methotrexate, doxorubicin, cisplatinum and ifosfamide since the primary treatment or to receive a primary treatment with methotrexate, doxorubicin and cisplatinum where ifosfamide is employed only in the post-operative phase in patients that are histologically poor responders to the primary treatment.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Methotrexate (MTX), cisplatinum (CDP), doxorubicin (DOX)

Primary outcome(s)
Clinical efficacy in terms of event free survival, disease free survival and overall survival.

Key secondary outcome(s))
To compare the toxicity of the two regiments.

Completion date
31/12/2006

Eligibility

Key inclusion criteria
1. Patients with typical radiographic and histological features of primary, high-grade central osteosarcoma
2. Tumour located in the extremity
3. No previous history of cancer and no prior treatments
4. Aged under 40
5. No co-existing disease contraindicating chemotherapy
6. No evidence of metastases at diagnosis
7. Informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
246

Key exclusion criteria
1. Metastatic osteosarcoma
2. Previous history of cancer
3. Co-existing disease contraindicating chemotherapy
4. No informed consent

Date of first enrolment
02/04/2001

Date of final enrolment
31/12/2006

Locations

Countries of recruitment
Italy

Study participating centre
Via Pupilli 1
Bologna
Italy
40136

Sponsor information

Organisation
Orthopaedic Institute Rizzoli (Istituti Ortopedici Rizzoli) (Italy)

ROR
https://ror.org/02ycyys66

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Orthopaedic Institute Rizzoli (Istituti Ortopedici Rizzoli) (Italy)

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		07/05/2012	01/09/2021	Yes	No