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ISG/AIEOP EW-1: Randomised controlled trial for patients with non-metastatic Ewing sarcoma

Submission date	Recruitment status	[ ] Prospectively registered
29/03/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
22/04/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/03/2016	Cancer	[ ] Record updated in last year

Plain English summary of protocol
Background and study aims
Ewing sarcoma is a rare type of bone cancer. It is treated with chemotherapy to kill the cancer cells. The aim of this study is to compare a prolonged chemotherapy treatment and a shorter dose-intense chemotherapy treatment for Ewing sarcoma.

Who can participate?
Patients aged under 41 with non-metastatic Ewing sarcoma (i.e., that has not spread)

What does the study involve?
Participants are randomly allocated to receive either the prolonged treatment or the shorter dose-intense treatment. The survival rate in both groups is assessed after four years.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Italian Sarcoma Group (Italy)

When is the study starting and how long is it expected to run for?
April 2009 to April 2016

Who is funding the study?
Italian Sarcoma Group (Italy)

Who is the main contact?
Dr Stefano Ferrari
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2008-008361-35

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomised controlled phase III trial of patients with non-metastatic Ewing sarcoma treated with either a prolonged treatment or a shorter dose-intense treatment and the effect on probability of survival

Acronym
ISG/AIEOP EW-1

Study objectives
ISG/AIEOP EW-1 is a randomised phase III trial. The hypothesis tested is that the same probability of survival expected with a prolonged treatment can be achieved with a shorter and dose/intense treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics board of the Istituto Ortopedico Rizzoli, Bologna, Italy, 17/12/2008, EudraCT no.: 2008-008361-35

Study design
Randomised controlled phase III trial

Primary study design

Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please contact annalisa.nobile@ior.it to request a patient information sheet

Health condition(s) or problem(s) studied
Non-metastatic Ewing sarcoma

Interventions
Standard arm and experimental arm are based on neoadjuvant chemotherapy. According to the histologic or radiographic response to primary chemotherapy patients will receive high-dose chemotherapy and peripheral stem cells transplantation.

Standard arm:
Alternating cycles with VAC (vincristine 1.5 mg/m^2 [top dose 2 mg], doxorubicin 80 mg/m^2, cyclophosphamide 1,200 mg/m^2), IVAc (ifosfamide 9 g/m^2, vincristine 1.5 mg/m^2 [top dose 2 mg], dactinomycin 1.5 mg/m^2 [top dose 2 mg]), IE (ifosfamide 9 g/m^2, etoposide 450 mg /m^2). In poor responder patients mobilising cycle with CE (cyclophosphamide 4,000 mg/m^2, etoposide 600 mg/m^2), high dose chemotherapy with busulfan (0.8 mg/kg x 4/day for 4 days) and melfalan (140 mg/m^2). Total duration of treatment: good responders 37 weeks, poor responders 25 weeks.

Experimental arm:
Alternating cycles with VAI (vincristine 1.5 mg/m^2 [top dose 2 mg], doxorubicin 80 mg/m^2, ifosfamide 9 g/m^2), IVAc (ifosfamide 9 g/m^2, vincristine 1.5 mg/m^2 [top dose 2 mg]), IE (ifosfamide 9 g/m^2, etoposide 450 mg/m^2). In poor responder patients mobilising cycle with CE (cyclophosfamide 4,000 mg/m^2, etoposide 600 mg/m^2), high dose chemotherapy with busulfan intravenous (I.V.) (0.8 mg/kg x 4/day for 4 days) and melfalan (140 mg/m^2). Total duration of treatment: good responders 25 weeks, poor responders 25 weeks.

Total duration of follow-up for all arms: 5 years enrolment, 2 years follow-up.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Vincristine, dactinomycin, doxorubicin, cyclophosfamide, ifosfamide, etoposide, busulfan, melfalan

Primary outcome measure
Overall survival, measured at four years

Secondary outcome measures
1. Event-free survival,measured at four years
2. Percent of patients with good response to primary chemotherapy
3. Received dose/intensity
4. Chemotherapy toxicity

Overall study start date
11/04/2009

Completion date
30/04/2016

Eligibility

Key inclusion criteria
1. Patients with non-metastatic Ewing sarcoma
2. Aged less than 41 years, either sex
3. No previous treatment for the disease
4. Informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
220

Key exclusion criteria
1. Metastatic Ewing sarcoma
2. Medical contraindications to the protocol drugs

Date of first enrolment
11/04/2009

Date of final enrolment
30/04/2016

Locations

Countries of recruitment
Italy

Study participating centre
Via Pupilli 1
Bologna
Italy
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Sponsor information

Organisation
Italian Sarcoma Group (Italy)

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Sponsor type
Research organisation

Website
http://www.italiansarcomagroup.org/

ROR
https://ror.org/01wa16j27

Funder(s)

Funder type
Research organisation

Funder Name
Italian Sarcoma Group (Italy)

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