

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

Submission date 29/03/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 22/04/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 18/03/2016	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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
stefano.ferrari@ior.it

Contact information

Type(s)

Scientific

Contact name

Dr Stefano Ferrari

Contact details

Via Pupilli 1

Bologna

Italy

40136

-

stefano.ferrari@ior.it

Additional identifiers**Clinical Trials Information System (CTIS)**

2008-008361-35

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

Primary study design

Interventional

Study design

Randomised controlled phase III trial

Study type(s)

Treatment

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/m² [top dose 2 mg], doxorubicin 80 mg/m², cyclophosphamide 1,200 mg/m²), IVAc (ifosfamide 9 g/m², vincristine 1.5 mg/m² [top dose 2 mg], dactinomycin 1.5 mg/m² [top dose 2 mg]), IE (ifosfamide 9 g/m², etoposide 450 mg/m²). In poor responder patients mobilising cycle with CE (cyclophosphamide 4,000 mg/m², etoposide 600 mg/m²), high dose chemotherapy with busulfan (0.8 mg/kg x 4/day for 4 days) and melphalan (140 mg/m²). Total duration of treatment: good responders 37 weeks, poor responders 25 weeks.

Experimental arm:

Alternating cycles with VAI (vincristine 1.5 mg/m² [top dose 2 mg], doxorubicin 80 mg/m², ifosfamide 9 g/m²), IVAc (ifosfamide 9 g/m², vincristine 1.5 mg/m² [top dose 2 mg]), IE (ifosfamide 9 g/m², etoposide 450 mg/m²). In poor responder patients mobilising cycle with CE (cyclophosphamide 4,000 mg/m², etoposide 600 mg/m²), high dose chemotherapy with busulfan intravenous (I.V.) (0.8 mg/kg x 4/day for 4 days) and melphalan (140 mg/m²). 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, cyclophosphamide, ifosfamide, etoposide, busulfan, melphalan

Primary outcome(s)

Overall survival, measured at four years

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

40136

Sponsor information**Organisation**

Italian Sarcoma Group (Italy)

ROR

<https://ror.org/01wa16j27>

Funder(s)

Funder type

Research organisation

Funder Name

Italian Sarcoma Group (Italy)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration