

A European Intergroup Cooperative Ewing's Sarcoma Study: A randomised study for the treatment of Ewing's sarcoma of bone

Submission date 01/07/2001	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 01/07/2001	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 01/02/2012	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT00002516

Protocol serial number

ET 9302

Study information

Scientific Title

Study objectives

Not provided at time of registration

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)

Health condition(s) or problem(s) studied

Bone cancer

Interventions

The trial is divided into two separate studies for standard risk and high risk patients. Following randomisation all patients receive induction chemotherapy with vincristine, adriamycin and ifosfamide alternating every 3 weeks with vincristine, actinomycin-D and ifosfamide (VAIA). A total of four courses, two of each drug combination.

A. STANDARD RISK PATIENTS: Following induction depending upon the initial randomisation patients are allocated to either:

1. Arm A: Chemotherapy with vincristine, adriamycin and cyclophosphamide alternating every 3 weeks with vincristine, actinomycin-D and cyclophosphamide (VACA). A total of ten courses, five of each drug combination.
2. Arm B: Chemotherapy with vincristine, adriamycin and ifosfamide alternating every 3 weeks with vincristine, actinomycin-D and ifosfamide (VAIA), a total of ten courses, five of each drug combination.

B. HIGH RISK PATIENTS: Following induction depending upon the initial randomisation patients are allocated to either:

1. Arm B: Chemotherapy, VAIA as described in Arm B for standard risk patients.
2. Arm C: Chemotherapy etoposide, vincristine, adriamycin and ifosfamide alternating every 3 weeks with etoposide, vincristine, actinomycin-D and ifosfamide (EVAIA). A total of ten courses, five of each drug combination.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Cancer drugs

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

Completion date

30/06/1999

Eligibility

Key inclusion criteria

1. Biopsy proven Ewing's sarcoma, atypical Ewing's sarcoma or peripheral neuroectodermal tumour
2. No previous radiotherapy, chemotherapy or surgery
3. No primary definitive local therapy
4. Aged < 35 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex**Key exclusion criteria**

Patients with soft tissue Ewing's sarcoma or other small cell sarcomas are not eligible

Date of first enrolment

01/01/1994

Date of final enrolment

30/06/1999

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
UKCCCR Register Co-ordinator
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Cancer Research UK (CRUK) (UK)

ROR
<https://ror.org/054225q67>

Funder(s)

Funder type
Research organisation

Funder Name
Cancer Research UK

Alternative Name(s)
CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Funder Name
European Community (BIOMED)

Funder Name
Deutsche Krebshilfe

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	preliminary results	01/07/1999		Yes	No
Results article	results	01/01/2003		Yes	No
Results article	results	01/12/2005		Yes	No
Results article	results	01/04/2008		Yes	No
Results article	results	20/09/2008		Yes	No