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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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 01/07/2001	**Overall study status** Completed	
Last Edited 01/02/2012	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00002516

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/1994

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

Age group
Adult

Sex
Not Specified

Target number of participants
Not provided at time of registration

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
England

United Kingdom

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

Sponsor information

Organisation
Cancer Research UK (CRUK) (UK)

Sponsor details
PO Box 123
Lincoln's Inn Fields
London
United Kingdom
WC2A 3PX
+44 (0)207 317 5186
kate.law@cancer.org.uk

Sponsor type
Charity

Website
http://www.cancer.org.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, 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

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

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