

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 01/07/2001	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 01/02/2012	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr - -

Contact details

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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