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

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

# 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)

Study type(s)

#### 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

#### 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, 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**

# Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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

Results article		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