ISRCTN61438620 https://doi.org/10.1186/ISRCTN61438620

EURO-EWING 99: European ewing tumour working initiative of national groups

Submission date 19/08/2002	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/08/2002	**Overall study status** Completed	
Last Edited 29/10/2021	**Condition category** Cancer	

Plain English summary of protocol
http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-treatment-for-patients-with-ewings-sarcoma-or-peripheral-primitive-neuroectodermal-tumour

Study website
http://www.birmingham.ac.uk/research/activity/mds/trials/crctu/trials/ee99/index.aspx

Contact information

Type(s)
Scientific

Contact name
Dr Bernadette Brennan

Contact details
Royal Manchester Children's Hospital
Oxford Road
Manchester
United Kingdom
M13 9WL

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00020566

Secondary identifying numbers

ET2000/03 (EE99)

Study information

Scientific Title
Combination chemotherapy with or without peripheral stem cell transplantation, radiation therapy, and/or surgery in treating patients with Ewing's sarcoma

Acronym
EURO-EWING 99

Study objectives
This randomized phase III trial is studying different combination chemotherapy regimens to see how well they work when given with or without peripheral stem cell transplantation, radiation therapy, and/or surgery in treating patients with Ewing's sarcoma.

Please note as of 08/02/2011 the anticipated end date for this trial has been updated from 31/03/2010 to 30/03/2017.

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)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Ewing's sarcoma

Interventions
Three randomisations, two arms per randomisation:
Randomisation 1: vincristine, dactinomycin, and ifosfamide (VAI) versus vincristine,

dactinomycin, and cyclophosphamide (VAC)
Randomisation 2 (loc): VAI versus busulfan, melphalan (Bu-Mel)
Randomisation 2 (pulm): VAI and lung radiation versus Bu-Mel (NO lung radiation)

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Vincristine, dactinomycin, ifosfamide, cyclophosphamide, busulfan, melphalan

Primary outcome measure
1. Event-free survival
2. Overall survival

Secondary outcome measures
1. Feasibility, toxicity, and response at one month following induction therapy
2. Feasibility and toxicity of consolidation regimens at one month following consolidation therapy

Overall study start date
01/02/2001

Completion date
30/03/2017

Eligibility

Key inclusion criteria
1. Histologically confirmed Ewing's tumour of the bone or soft tissue
2. Age less than 50
3. Completed pre-treatment investigations allowing prognostic group definition
4. No previous chemotherapy
5. Informed consent
6. Normal cardiac and renal function
7. Interval between date of definitive biopsy and registration less than 45 days
8. Interval between date of definitive biopsy and start of chemotherapy less than 30 days

Participant type(s)
Patient

Age group
Not Specified

Sex
Both

Target number of participants

1200

Total final enrolment
1695

Key exclusion criteria
Does not comply with above inclusion criteria

Date of first enrolment
01/02/2001

Date of final enrolment
30/03/2017

Locations

Countries of recruitment
Australia

Austria

Belgium

Canada

Denmark

England

France

Germany

Ireland

Netherlands

New Zealand

Portugal

Switzerland

United Kingdom

United States of America

Study participating centre

Cancer Research UK Clinical Trials Unit (CRCTU)
University of Birmingham
Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation
University of Birmingham

Sponsor details
Edgbaston
Birmingham
United Kingdom
B15 2TT

Sponsor type
Charity

Website
http://www.ukccsg.org

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Charity

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

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal.

Intention to publish date
01/01/2010

Individual participant data (IPD) sharing plan
Not provided at time of registration

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	results	01/07/2006		Yes	No
Results article	results	10/07/2010		Yes	No
Results article	results	01/09/2015		Yes	No
Results article	results	01/10/2017		Yes	No
Plain English results		28/03/2019	29/10/2021	No	Yes