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

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

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

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