

Study for rhabdomyosarcoma and other malignant soft tissue tumours of childhood

Submission date 01/07/2001	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 01/07/2001	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 21/01/2019	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Contact details
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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00025441

Protocol serial number
STS9507

Study information

Scientific Title
Study for rhabdomyosarcoma and other malignant soft tissue tumours of childhood

Study objectives

Not provided at time of registration

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)**Health condition(s) or problem(s) studied**

Cancer, soft tissue

Interventions

High risk non metastatic patients are randomised to one of two treatment groups:

1. Group A: Chemotherapy with ifosfamide, vincristine and actinomycin D (IVA)
2. Group B: Chemotherapy with carboplatin, epirubicin, vincristine, ifosfamide, etoposide and actinomycin D

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Ifosfamide, vincristine, actinomycin D, carboplatin, epirubicin, etoposide

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/12/2000

Eligibility**Key inclusion criteria**

1. Soft tissue sarcoma at one of the following sites: Vagina - Uterus - Paratestis - Orbit - Head and Neck - Bladder - Prostate - Limbs
2. Histological types: Rhabdomyosarcoma - Embryonal sarcoma - Undifferentiated sarcoma -

Extra osseous Ewing's sarcoma - Soft tissue primitive neuroectodermal tumours

3. Stages I and II

4. Aged 6 months to 18 years

5. Less than 8 weeks since diagnostic biopsy

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

6 Months

Upper age limit

18 Years

Sex

All

Key exclusion criteria

Does not match inclusion criteria

Date of first enrolment

01/07/1995

Date of final enrolment

31/12/2000

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

MRC Clinical Trials Unit

London

United Kingdom

NW1 2DA

Sponsor information

Organisation

Cancer Research UK (CRUK) (UK)

ROR

<https://ror.org/054225q67>

Funder(s)**Funder type**

Charity

Funder Name

Cancer Research UK (CRUK) (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

United Kingdom Children's Cancer Study Group (UKCCSG) (UK)

Results and Publications**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	results	01/06/2010	21/01/2019	Yes	No