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Study for rhabdomyosarcoma and other malignant soft tissue tumours of childhood

Submission date	Recruitment status	[_] Prospectively registered
01/07/2001	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/07/2001	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
21/01/2019	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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United Kingdom
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00025441

Secondary identifying numbers
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

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
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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/07/1995

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

Age group
Child

Lower age limit
6 Months

Upper age limit
18 Years

Sex
Both

Target number of participants
Not provided at time of registration

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
England

United Kingdom

Study participating centre
MRC Clinical Trials Unit
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
Charity

Funder Name

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

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	results	01/06/2010	21/01/2019	Yes	No