ISRCTN15121868 https://doi.org/10.1186/ISRCTN15121868

# 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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## 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

### Study design
Randomised controlled trial

### Primary study design
Interventional

### 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 |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |