

# A trial looking at the treatment of children and young people with non-rhabdomyosarcoma soft tissue sarcomas

<b>Submission date</b> 19/05/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 19/05/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 18/07/2019	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-the-treatment-of-children-and-young-people-with-non-rhabdomyosarcoma-soft-tissue-sarcomas>

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

### ClinicalTrials.gov (NCT)

NCT00334854

### Clinical Trials Information System (CTIS)

2005-001139-31

### Protocol serial number

2245

# Study information

## Scientific Title

A multicentre non-randomised interventional treatment trial looking at the treatment of children and young people with non-rhabdomyosarcoma soft tissue sarcomas

## Acronym

STS 2006 03 (NRSTS)

## Study objectives

The protocol comprises three separate sections: synovial sarcoma, adult type sarcoma and other histotypes. In the other histotype section are guidelines for treatment, and for some tumours, more defined treatment plans, however, this should be considered as a suggestion only.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Trent MREC approved on the 26th September 2005 (ref: 05/MRE04/37)

## Study design

Multicentre non-randomised interventional treatment trial

## Primary study design

Interventional

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Topic: National Cancer Research Network; Subtopic: Sarcoma, Paediatric Oncology; Disease: Soft Tissue

## Interventions

Synovial and adult type sarcoma patients will be treated according to a risk-adapted treatment program. If chemotherapy is given it will be up to 4 cycles (for synovial sarcoma) and 5 cycles (for adult type sarcoma) of ifosfamide-doxorubicin and 2 cycles of ifosfamide alone.

Study entry: registration only

## Intervention Type

Other

## Phase

Phase III

## Primary outcome(s)

Evaluate the survival rates and the pattern of treatment failure, measured after 3 years follow up

## Key secondary outcome(s)

Measured after 3 years follow up:

1. Verify the impact of omission of adjuvant chemotherapy in patients with low-risk synovial sarcoma
2. Investigate the role of adjuvant chemotherapy in IRS group I-II, G3, size greater than 5 cm adult type sarcoma
3. Prospective evaluation of clinical/pathological prognostic factors
4. Investigate the role of ifosfomide-doxorubicin regimen in improving the response rate
5. Unify the treatment of NRSTS patients in Europe

**Completion date**

31/03/2011

## **Eligibility**

**Key inclusion criteria**

Eligibility criteria for the prospective non-randomised historically-controlled trial are the following:

1. A pathologically proven diagnosis of synovial sarcoma and adult-type soft tissue sarcomas
2. No evidence of metastatic lesions
3. Age less than 21 years (20 years and 364 days) of age
4. No previous treatment except for primary surgery
5. For patients who require adjuvant chemotherapy according to protocol guidelines, no more than a 8 week-interval between the diagnostic surgical approach and the start of chemotherapy
6. For patients who require adjuvant chemotherapy according to protocol guidelines, no pre-existing illness preventing treatment (in particular renal function must be equivalent to grade 0 - 1 nephrotoxicity, no prior history of cardiac disease and normal shortening fraction [greater than 28%] and ejection fraction [greater than 47%])
7. No previous malignancy. Patients with post-irradiation soft part sarcomas could be registered and treated according to the protocol guidelines, but they will be analysed separately.
8. Diagnostic material available for pathology review
9. Available for long term follow up through the treatment centre
10. Written informed consent for treatment available

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Other

**Sex**

All

**Key exclusion criteria**

Does not meet inclusion criteria

**Date of first enrolment**

01/03/2006

**Date of final enrolment**

31/03/2011

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Royal Manchester Children's Hospital**

Manchester

United Kingdom

M13 9WL

## Sponsor information

**Organisation**

Central Manchester University Hospitals NHS Foundation Trust

**ROR**

<https://ror.org/00he80998>

## Funder(s)

**Funder type**

Charity

**Funder Name**

Cancer Research 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

Central Manchester University Hospitals NHS Foundation Trust

## 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?
<a href="#">Plain English results</a>			18/07/2019	No	Yes