ISRCTN55318937 https://doi.org/10.1186/ISRCTN55318937

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

Submission date 19/05/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 19/05/2010	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 18/07/2019	**Condition category** Cancer	[_] Individual participant data [_] 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
Dr Bernadette Brennan

Contact details
Royal Manchester Children's Hospital
Oxford Road
Manchester
United Kingdom
M13 9WL

Additional identifiers

Clinical Trials Information System (CTIS)
2005-001139-31

ClinicalTrials.gov (NCT)
NCT00334854

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 Unversity 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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results			18/07/2019	No	Yes