

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 19/05/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 18/07/2019	Condition category 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

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 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?
Plain English results			18/07/2019	No	Yes