ISRCTN76456502 https://doi.org/10.1186/ISRCTN76456502

Radiotherapy given to a reduced area following surgery in adult patients with limb, hand or foot soft tissue sarcoma to find out if it will cause fewer side effects, without increasing the risk of the sarcoma coming back

Submission date
28/09/2005

Recruitment status
No longer recruiting

Registration date
06/10/2005

Overall study status
Completed

Last Edited
13/04/2022

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
http://www.cancerhelp.org.uk/trials/a-trial-looking-at-the-size-of-the-radiotherapy-treatment-area-for-people-with-soft-tissue-sarcoma

Study website
http://www.vortex.bham.ac.uk/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00423618

Secondary identifying numbers
SA3002

Study information

Scientific Title
Randomised trial of volume of post-operative radiotherapy given to adult patients with extremity soft tissue sarcoma

Acronym
VORTEX

Study objectives
The timing of the radiotherapy in relation to surgery, the extent of surgery required, the extent of apparently normal tissue around the tumour bed to be included in the irradiated volume, and the best dose and fractionation schedule are still unresolved issues. There have been no systematic reviews or randomised trials in the field of extremity soft tissue sarcoma in adult patients. It is now time to obtain data from a prospective study of radiotherapy margins in the treatment of adult extremity soft tissue sarcoma. There is no evidence that the international practice of irradiating large volumes of normal tissue is necessary. The VORTEX study has been designed to address this question. A positive result would change international practice and significantly reduce the morbidity of radiotherapy treatment in this group of patients.

Protocol can be found at: http://www.birmingham.ac.uk/Documents/college-mds/trials/crctu/vortex/pdfsindexvortex/VORTEXProtocolversion602082010.pdf

On 15/02/2011 the anticipated end date was updated from 09/01/2010 to 31/07/2011.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North-East York REC, 08/03/2006, ref: 06/MRE03/3

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Extremity soft tissue sarcoma

Interventions
Patients will have a number of baseline assessments prior to surgery, including:
1. History
2. Physical examination
3. Performance status
4. Vital signs
5. Haematology (full blood count [FBC] with differential)
6. Biochemistry
7. Chest X-ray
8. Computed tomography (CT) scan thorax
9. Magnetic resonance imaging (MRI) local site
10. Completion of the Toronto Extremity Salvage Score (TESS) questionnaire

Post surgery patients will undergo the following assesments:
1. Physical examination
2. Performance status
3. Vital signs
4. Wound assesment
5. Completion of the Toronto Extremity Salvage Score (TESS) questionnaire
6. Completion of the patient perceived change of status

Randomisation will take place after surgery and within a time frame so that treatment can commence within 12 weeks of surgery. Patients who fulfill all the eligibility citeria will then be randomised by the CRCTU into one of the two treatment arms:

Radiotherapy treatment:
Control arm: a total of 33 fractions each of 2 Gy should be given once a day for 5 days per week over 6 weeks and 3 days in week 7, totalling 66 Gy. Treatment should not be given routinely at weekends. The first 25 fractions (50 Gy) will be given to a Clinical Target Volume (CTV) which gives a 5 cm margin to the GTV the surgical bed cranio-caudally or 1 cm margin to the scar, whichever is longer in the cranial caudal direction. Axially a minimum of 2 cm for the CTV unless there is an intact fascial boundary. The phase 2 of 16 Gy in 8 fractions will treat a CTV volume, giving a 1.5 cm margin to the surgical bed longitudinally and 2 cm laterally on an intact fascial boundary.

Research arm: a total of 33 fractions each of 2 Gy should be given once a day for 5 days per week over 6 weeks and 3 days in week 7, totalling 66 Gy. The experimental treatment arm shall be to treat a CTV volume giving a 1.5 cm margin to the surgical bed longitudinally and 2 cm laterally on

an intact fascial boundary. The entire treatment shall be given to the volume described as phase 2 in the control arm.

During radiotherapy the acute skin morbidity will be checked weekly.

Follow-up assesments:
6 months post-operation:
1. Physical examination
2. Performance status
3. Vital signs
4. Late radiation morbidity
5. Chest X-ray
6. MRI local site
7. Completion of the Toronto Extremity Salvage Score (TESS) questionnaire
8. Completion of the patient perceived change of status

9 months post-operation:
1. Physical examination
2. Performance status
3. Vital signs
4. Late radiation morbidity
5. Chest X-ray

12 months post-operation:
1. Physical examination
2. Performance status
3. Vital signs
4. Late radiation morbidity
5. Chest X-ray
6. MRI local site
7. Completion of the Toronto Extremity Salvage Score (TESS) questionnaire
8. Completion of the patient perceived change of status

15 months post-operation:
1. Physical examination
2. Performance status
3. Vital signs
4. Late radiation morbidity
5. Chest X-ray

18 months post-operation:
1. Physical examination
2. Performance status
3. Vital signs
4. Late radiation morbidity
5. Chest X-ray
6. MRI local site
7. Completion of the Toronto Extremity Salvage Score (TESS) questionnaire
8. Completion of the patient perceived change of status

24 months post-operation:
1. Physical examination

2. Performance status
3. Vital signs
4. Late radiation morbidity
5. Chest X-ray
6. MRI local site
7. Completion of the Toronto Extremity Salvage Score (TESS) questionnaire
8. Completion of the patient perceived change of status

Intervention Type
Other

Phase
Phase III

Primary outcome measure
1. Limb functionality: as measured by the Toronto Extremity Salvage Score (TESS)
2. Time to local recurrence: defined in whole days, as the time from randomisation into the trial to the occasion when a biopsy-confirmed local recurrence is first suspected by clinical examination; for those patients who are not observed to have a local relapse during the course of the study, the time to local recurrence will be censored at the last follow-up date
3. Local recurrence rate

Secondary outcome measures
1. Soft tissue and bone toxicity: measured by the RTOG scoring system
2. Disease-free survival time: defined in whole days as time from randomisation into the trial to either local or distant recurrence or death (whichever occurs first)
3. Overall survival time: defined in whole days as time from randomisation into the trial to death

Overall study start date
28/02/2005

Completion date
16/10/2018

Eligibility

Key inclusion criteria
1. Histologically proven soft tissue sarcoma. Imaging and pathology from first surgery are required.
2. Lesion originates in extremity. For upper extremity this includes lesions from the medial border of the scapula to tumours as far distal as the finger tips. It does not include lesions of the chest wall arising adjacent to the scapula but not originating in the shoulder bone. The lower extremity regions include hip girdle tumours commencing at the iliac crest, excluding lesions arising from within the pelvis, and extends to include lesions as far distal as the toes.
3. The patients who have undergone excisional biopsy with positive margins or other inadequate surgery (macroscopically involved margins) will be eligible for entry into this study only following further definitive re-excision. A microscopically irradical surgical margin is permitted but not a macroscopically involved one. Patients with positive margins in whom no further surgery is possible short of amputation or major functional loss may be included provided there is no macroscopic residual disease.
4. Patient has been evaluated by the surgeon and radiotherapist, who agree that a combination

of the two treatments is appropriate and that the patient is fit for protocol therapy
5. No prior radiotherapy to the local site
6. Signed and dated Patient Informed Consent
7. Protocol treatment is to begin within 12 weeks of surgery
8. Patient must be 16 years of age or older

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
400

Total final enrolment
216

Key exclusion criteria
1. Patient has rhabdomyosarcoma of the alveolar or embryonal subcategories, primitive neuro-ectodermal tumour (PNET) soft tissue Ewings sarcoma, extraskeletal osteosarcoma, aggressive fibromatosis (desmoid tumours) or dermatofibrosarcoma protruberans
2. Patients with local recurrence after previous treatment of a sarcoma are excluded (as they have a significantly higher risk of late recurrence)
3. Prior or concurrent malignancy except adequately treated non-melanomatous carcinoma of the skin or in situ carcinoma of the cervix
4. Stage of disease such that limb conservation treatment by a combination of surgery and radiotherapy is not appropriate
5. The surgery performed has left macroscopic tumour in situ
6. Use of neoadjuvant or adjuvant chemotherapy
7. Patient has regional nodal disease or unequivocal distant metastasis
8. Other major medical illness judged likely by the local investigator to preclude safe administration of protocol treatment
9. Local recurrence more than 3 months after previous definitive surgery (patients with local recurrence within 3 months of previous surgery and who undergo subsequent re-excision may be included as they are considered to have initial inadequate primary excision)

Date of first enrolment
20/07/2007

Date of final enrolment
16/07/2013

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
Cancer Research Centre
Sheffield
United Kingdom
S10 2SJ

Study participating centre
Addenbrooke's Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
Bristol Haematology & Oncology Centre
Horfield Road
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United Kingdom
BS2 8ED

Study participating centre
Cheltenham General Hospital
Sandford Road
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United Kingdom
GL53 7AN

Study participating centre
Churchill Hospital
Old Road
Headington
Oxford
United Kingdom
OX3 7LE

Study participating centre
Christie Hospital
Wilmslow Road
Manchester
United Kingdom
M20 4BX

Study participating centre
Freeman Hospital
Freeman Road
Newcastle Upon Tyne
United Kingdom
NE7 7DN

Study participating centre
Leicester Royal Infirmary
Infirmary Square
Leicester
United Kingdom
LE1 5WW

Study participating centre
Manchester Royal Infirmary
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
Mount Vernon Hospital
Rickmansworth Road
Northwood
United Kingdom
HA6 2RN

Study participating centre
Robert Jones & Agnes Hunt Orthopaedic Hospital
Gobowen
Oswestry
United Kingdom
SY10 7AG

Study participating centre
Norfolk & Norwich University Hospital
Colney Lane
Norwich
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United Kingdom
NR4 7UY

Study participating centre
Royal Devon and Exeter Hospital
Barrack Road
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EX2 5DW

Study participating centre
University Hospital of North Staffordshire
Newcastle Road
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Study participating centre
Royal Orthopaedic Hospital Birmingham
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Study participating centre
Queen Elizabeth Hospital Birmingham
Mindelsohn Way
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B15 2TH

Study participating centre

Royal Derby Hospital
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DE22 3DT

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Royal Preston Hospital
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PR2 9HT

Study participating centre
Royal Marsden Hospital
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United Kingdom
SW3 6JJ

Study participating centre
St. James's University Hospital
Beckett Street
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LS9 7TF

Study participating centre
Torbay Hospital
Lowes Bridge
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TQ2 7AA

Study participating centre
University College London Hospitals
250 Euston Road

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United Kingdom
NW1 2PG

Study participating centre
The Beatson West Of Scotland Cancer Centre
1053 Great Western Road
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G12 0YN

Study participating centre
Weston Park Hospital
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S10 2SJ

Sponsor information

Organisation
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Sponsor details
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231 West Street
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Sponsor type
University/education

ROR
https://ror.org/05krs5044

Funder(s)

Funder type

Charity

Funder Name
Cancer Research 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

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from vortex@trials.bham.ac.uk

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results		01/10/2016	13/04/2022	No	No