Study Summary

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

Aims/Objectives: The aim of this trial is to assess if a reduced volume of post-operative radiotherapy increases limb function without compromising local control

Outcomes:
Primary: Limb functionality and time to local recurrence
Secondary: Soft tissue and bone toxicity, disease free-survival, overall survival time and overall level of disability

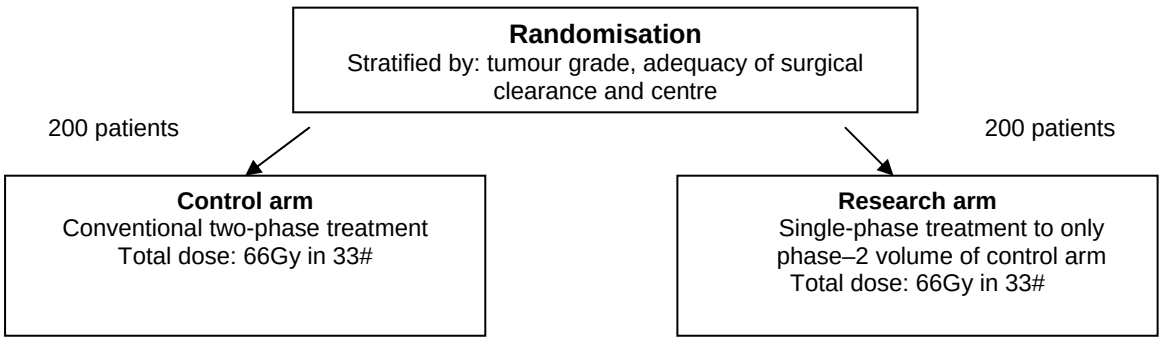
Main *(but not exhaustive)* inclusion criteria:

- Histologically proven soft tissue sarcoma. Imaging and pathology from first surgery are required
- Microscopically irradical surgical margin
- Lesion originates in extremity
- No prior radiotherapy to the local site
- Protocol treatment is to begin within 12 weeks of surgery
- Patients must be 16 years of age or older
- Male and female of reproductive potential must use medically acceptable contraception during the duration of radiation treatment and for three months following the completion of the radiation treatment

Main *(but not exhaustive)* exclusion criteria:

- Local recurrence after previous treatment of sarcoma or more than 3 months after previous definitive surgery
- Surgery has left macroscopic tumour in situ
- Patient has regional nodal disease or unequivocal distant metastasis
- Use of neoadjuvant or adjuvant chemotherapy
- Prior or concurrent malignancy (except adequately treated non-melanomatous carcinoma of the skin or in situ carcinoma of the cervix) within the last 3 years.

Diagrammatic representation of treatment allocation (if applicable):



Investigations required prior to randomisation:

- Haematology: FBC with differential
- Wound assessment
- Radiology: chest X-ray, CT thorax and MRI local Site
- Toronto Extremity Salvage Score
- Patient Rating Change of function

National Trial Co-ordinator details:

Name: Ana Hughes, VORTEX Trial Co-ordinator
Cancer Research UK Clinical Trials Unit, Institute for Cancer Studies, University of Birmingham, Edgbaston, Birmingham, B15 2TT
Tel: 0121 4143793 **Fax**: 0121 4142230 **E-mail**:VORTEX@trials.bham.ac.uk