**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 irradiical 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):**

<table>
<thead>
<tr>
<th>Control arm</th>
<th>Research arm</th>
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<tbody>
<tr>
<td>Conventional two-phase treatment</td>
<td>Single-phase treatment to only phase–2 volume of control arm</td>
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<tr>
<td>Total dose: 66Gy in 33#</td>
<td>Total dose: 66Gy in 33#</td>
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**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

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