A phase II study to investigate the feasibility, efficacy and toxicity of a combined regimen of radiotherapy and chemotherapy for patients with carcinosarcoma of the endometrium

Investigators

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Study Plan

- A prospective single-arm phase II study of adjuvant therapy in patients with FIGO stage IA (with myometrial invasion) to IVA (excluding stage IIIC2) carcinosarcoma of the uterus

Primary Objective

- To evaluate the feasibility of two cycles of Carboplatin and Abraxane followed by radiotherapy delivered with concurrent Cisplatin, then a further two cycles of Carboplatin and Abraxane, in patients with FIGO stage IA (with myometrial invasion) to IVA (excluding stage IIIC2) carcinosarcoma of the uterus

Secondary Objectives

- To evaluate the efficacy of the treatment protocol as measured by time to local, loco-regional and distant recurrence, failure-free survival and overall survival
- To evaluate the safety and tolerability of the treatment protocol as measured by the incidence and severity of acute and late toxicity

Schema

Surgery consisting of TAH/TLH, BSO, washings, omentectomy (if carcinosarcoma diagnosis known pre-operatively) +/- pelvic lymph node dissection

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PET-CT scan (CT C/A/P if PET-CT unavailable), Blood tests (FBE, U+E, LFT, Ca), Tests to assess suitability for chemotherapy

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Eligible patients invited to participate in trial. Patients who provide consent enrolled.

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2 x cycles of Carboplatin and Abraxane chemotherapy

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Radiotherapy with concurrent weekly low-dose Cisplatin chemotherapy

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2 x cycles of Carboplatin and Abraxane chemotherapy

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Follow up, consisting of:
A. Clinical review at 3, 6, 9, 12, 15, 18, 21, 24, 30, 36, 48, 60 months post treatment
B. Repeat PET/CT scan (CT C/A/P if PET-CT unavailable) at 6 months post treatment

Inclusion Criteria

- Newly diagnosed, histologically confirmed carcinosarcoma of the uterus, with myometrial invasion corresponding to FIGO stage IA (with myometrial invasion), IB, II, III (IIIC2 excluded) or IVA disease. Any involved lymph nodes must be located below the pelvic brim.
- Prior total abdominal hysterectomy and bilateral salpingo-oophorectomy with or without a dissection of pelvic and/or para-aortic lymph nodes.

- No residual disease on staging PET/CT or CT Chest/Abdomen/Pelvis above external iliac lymph nodes.
- ECOG performance status 0-2.
- Life expectancy > 6 months.
- Baseline blood tests within normal limits.
- Provision of written consent.

Exclusion Criteria

- Surgery or post-operative PET-CT (or CT C/A/P if PET-CT unavailable) reveals any disease outside the pelvis, except for +ve peritoneal washings.
- The patient is receiving any another investigational agent.
- The patient has an existing symptomatic peripheral neuropathy ≥ grade 2.
- The patient has a past history of invasive malignancy (except for non-melanomatous skin cancer) within the preceding five years.
- The patient has a past history of allergy to carboplatin or taxane-based chemotherapy.
- The patient has a serious illness or medical condition that precludes safe administration of trial treatment.
- The patient has a past history of radiotherapy treatment to the pelvis.
- The patient has a past history of inflammatory bowel disease