PORTEC-3

Randomised Phase III Trial Comparing Concurrent Chemoradiation and Adjuvant Chemotherapy with Pelvic Radiation Alone in High Risk and Advanced Stage Endometrial Carcinoma

PRIMARY OBJECTIVE

- Survival

SECONDARY OBJECTIVE

- Rates of pelvic recurrence
- Rates of distant metastases
- Assess treatment related toxicity
- Assess Quality of Life issues

FUTURE BIOLOGICAL STUDY

The main thrust of the study is clinical, however it is hoped in the future to carry out translational research focussing on the identification of new prognostic markers and novel molecular targets. To this aim, we plan to collect paraffin embedded blocks and serum samples taken before and 3 months post treatment from patients who consent to participate in this part of the trial.

SAMPLE SIZE

670 patients

PARTICIPATING COUNTRIES

The Netherlands, United Kingdom, Italy, Australia & New Zealand, Canada, France.

CONTACT DETAILS

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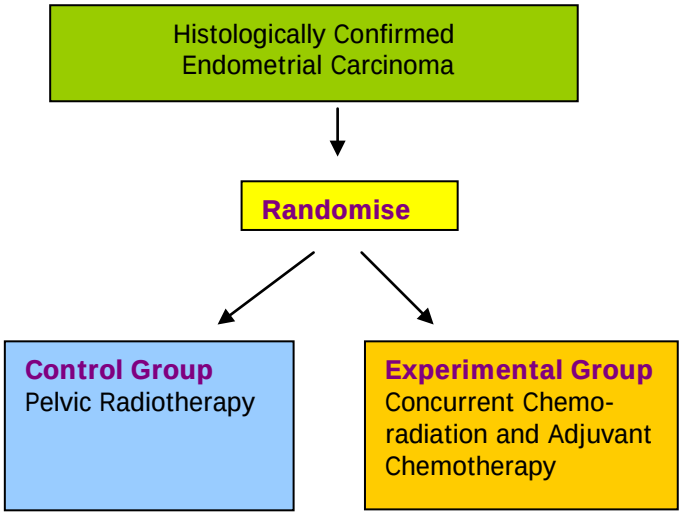
STUDY DESIGN



Control Group

Pelvic radiotherapy 45-50.4 Gy (1.8Gy/Fraction) in 25-28 days; Brachytherapy boost if cervical invasion.

Experimental Group

Radiotherapy as above; IV Cisplatin 50mg/m^2 days 1 & 22 of radiotherapy; Post radiotherapy: 4 x IV Carboplatin AUC5 and Paclitaxel 175mg/m^2 (at 21 day intervals).

Assessments at completion of radiotherapy & with each cycle of chemotherapy. Follow-up 3 monthly for 2 years; 6 monthly to 5 years & assessment at 7 and 10 years. Follow-up to include Quality of Life

ELIGIBILITY CRITERIA – Summarised

- Stage IA with myometrial invasion, grade 3 with documented LVSI
- Stage IB grade 3
- Stage II
- Stage IIIA or IIIC; or IIIB if parametrial invasion
- Stage IA with myometrial invasion, IB, II or IIIA/C with serous or clear cell histology
- Recommended surgery – TAH-BSO
- WHO-performance status 0-2
- WBC $\geq$ 3.0 x 10^9/L
- Platelets $\geq$ 100 x 10^9/L
- Bilirubin $\leq$ 1.5 x UNL
- ASAT/ALAT $\leq$ 2.5 x UNL
- Written informed consent

EXCLUSION CRITERIA –Summarised

- Uterine sarcoma (including carcinosarcoma)
- Previous malignancy, except non-melanomatous skin cancer within the last 10 years
- Previous pelvic radiotherapy
- Hormonal therapy or chemotherapy for tumour
- Macroscopic gross cervical involvement for which radical (Wertheim type) hysterectomy performed (eligible if stage II grade 3 or stage III)
- Crohn's disease or ulcerative colitis
- Residual macroscopic tumour after surgery
- GFR $\leq$ 60ml/min by C&G OR $\leq$ 50ml/min by EDTA or measured creatinine clearance
- Impaired cardiac function
- Peripheral neuropathy $\geq$ 2
- Hearing Impairment $\geq$ grade 3, or born deaf