Interim statistical analysis on a phase III randomised trial investigating the addition of modulated electro-hyperthermia to chemoradiation for cervical cancer in HIV positive and negative women in South Africa

C.A. Minnaar1, J.A. Kotzen1, A. Baeyens2
1Radiation Sciences, University of Witwatersrand Medical School, Johannesburg, South Africa, 2Radiation Biophysics, IThemba LABS, Cape Town, South Africa

Background: Cervical cancer is the second most common cancer in South Africa where funding and resources for treatment are limited and HIV infection rates are high. A Cochrane review (2010) on pooled data from six randomised trials showed a potential benefit to the addition of hyperthermia (HT) to radiotherapy (RT) protocols for cervical cancer. The Dutch Deep Hyperthermia trial (2010) reported a cost saving per quality adjusted life year when HT was added to RT protocols. The potential cost saving resulting from the addition of HT to cervical cancer treatment protocols may lower the burden on healthcare facilities in South Africa and improve treatment options in HIV positive patients.

Trial design: The aim is to determine the clinical effects of the addition of modulated electro-hyperthermia (mEHT) on the standard treatment protocols for locally advanced cervical cancer patients in state healthcare in South Africa. The objectives are to assess the effects of the addition of mEHT on local disease control, quality of life, acute and late toxicity and survival. Method: This is an ongoing phase III randomised clinical trial conducted at the Charlotte Maxeke Johannesburg Academic Hospital. The study aims to enrol 236 female participants with FIGO stage IIB (initial distal parametrium involvement) to IIIB cervical cancer (no bilateral hydronephrosis). Participants are being randomised into a “Hyperthermia” group (mEHT plus chemoradiation) and a “Control” group (chemoradiation alone), based on HIV status, age and stage of disease. All participants are receiving 25 fractions of 2Gy external beam radiation, 3 doses of high dose rate brachytherapy (8Gy) and up to 3 doses of cisplatin (80mg/m2). The Hyperthermia group is receiving two 55 minute local mEHT treatments per week during radiation therapy. Local disease control is being assessed by Positron Emission Tomography (PET) scans. Adverse events, quality of life and overall survival are being recorded and the data is being analysed. Ethics was obtained by the Human Research and Ethics Council (clearance number: M120477)

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