Update on phase III randomized clinical trial investigating the effects of the addition of electro-hyperthermia to chemoradiotherapy for cervical cancer patients in South Africa

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Cite this article as:
Minnaar C. A., Baeyens A., Kotzen J. (2017) Update on phase III randomized clinical trial investigating the effects of the addition of electro-hyperthermia to chemoradiotherapy for cervical cancer patients in South Africa
http://www.physicamedica.com/article/S1120-1797(16)30175-2/pdf

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Introduction. The Electro-Hyperthermia trial an ongoing phase III randomised clinical trial being conducted at the Charlotte Maxeke Johannesburg Academic Hospital. The general aim is to determine the clinical effects of the addition of modulated electro-hyperthermia (EHT) to 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 EHT on local disease control, quality of life, acute and late toxicity and overall survival.

Materials and methods. The study aims to enrol 236 female participants with FIGO stage IIB distal to IIIB cervical cancer. Participants are being randomised into a "Hyperthermia" group (EHT plus chemoradiation) and a "Control" group (chemoradiation alone), randomisation stratums: HIV status; age; stage of disease. All participants are receiving 50 Gy external beam radiation, 3 doses of high dose rate brachytherapy (8 Gy) and cisplatin. The Hyperthermia group is receiving two 55 minute local EHT 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.

Results. We report preliminary data of the first 100 participants to reach 6 months post treatment. We see a positive trend in survival and local disease control in the group receiving hyperthermia. There are no significant differences in acute adverse events or quality of life between the groups.

Conclusion. The preliminary results on the addition of EHT are positive with no impact on adverse events, however this must be confirmed with more patients on completion of the study.