Modulated electro-hyperthermia as a chemoradiosensitiser for locally advanced cervical cancer

Minnaar C.A.[1]; Kotzen J.A.[1]; Baeyens A.[1 2]
[1] Radiation Sciences, University of the Witwatersrand, South Africa
[2] Basic Medical Sciences, Ghent University, Belgium

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MODULATED ELECTRO-HYPERTHERMIA AS A CHEMORADIOSENSITISER FOR LOCALLY ADVANCED CERVICAL CANCER

Minnaar C.A.[1]; Kotzen J.A.[1]; Baeyens A.[1 2]
[1] Radiation Sciences, University of the Witwatersrand, South Africa
[2] Basic Medical Sciences, Ghent University, Belgium

OBJECTIVES:

The ongoing study is a phase III randomised clinical trial investigating the effects of the addition of mEHT to standard chemo-radiotherapy (CRT) protocols for locally advanced cervical cancer in HIV positive and negative women.

We report on the first 88 participants to reach 6 months post treatment.

DESIGN & METHODOLOGY

Inclusion criteria: FIGO stage IIB distal to IIIB of disease.

Exclusion criteria: Bilateral hydronephrosis; creatinine clearance < 60mL/min; HIV positive participants with a CD4 count <200 cells/mm^3 or who have not been on ARVs for at least 6 months.

Randomisation: Participants are being randomised into a treatment group (mEHT plus CRT) and a control group (CRT alone), based on HIV status, age and stage of disease.

Treatment: All participants are receiving 25 fractions of 2Gy external beam radiation, 3 doses of high dose rate brachytherapy (8Gy) and 1 to 2 doses of cisplatin. The treatment group is receiving two 55 minute mEHT treatments per week during radiotherapy.

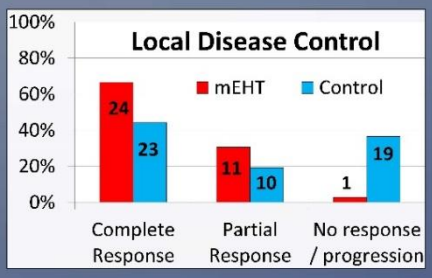
Outcomes: The local disease control has been classified as Complete Response, Partial Response, No Response/ Progressive Disease based on the RECIST and PERCIST criteria. Early toxicity is graded according to the CTCAE v4 criteria and late toxicity is assessed from 6 months post treatment onwards.

RESULTS:

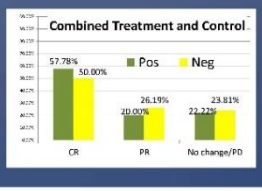
The study has a combined screening failure and drop-out rate of 28%.

88 participants have PET/CT results for 6 months post treatment (n=36 in mEHT group and n= 52 in the control group)

Survival: The 6 month survival in the study group is 100% versus 90% in the control. These results are absolute and not actuarial.



Local Disease Control by HIV Status



Toxicities: No unexpected early toxicities were reported in either group. No Significant difference in late toxicity at 6 months between the Treatment and Control groups or between the HIV+/- groups.

CONCLUSION:

The preliminary results continue to show a positive trend in local disease control and survival at 6 months in the treatment group without any unexpected adverse events or toxicity.

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