

HORTIS-III: Radiation Cystitis – a multicenter, prospective, double-blind, randomized, sham-controlled trial to evaluate the effectiveness of hyperbaric oxygen therapy in patients with refractory radiation cystitis

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Objective: Hyperbaric oxygen therapy (HBOT) for refractory late radiation cystitis has been reported with success rates of 60% to 92%. HORTIS (Hyperbaric Oxygen Radiation Tissue Injury Study) is a multicenter study conducted by the Baromedical Research Foundation, South Carolina, USA. Tygerberg Hospital and University of Stellenbosch is one of 6 centers recruiting patients for the radiation cystitis arm (HORTIS-III).

Methods: Patients were prospectively randomized: Group A (treatment) received HBOT (100% oxygen at 2.0 atmospheres). Group B (control) received sham treatment (21% oxygen at 1.0 atmosphere). Patients and referring physicians were blinded to the randomization process. Patients received 30-40 sessions of either HBOT or sham treatment. After unblinding, patients in the control group were offered crossover to the treatment group. Primary outcome measures included clinical evaluation, SOMALENT and EPIC scores.

Results: In total, 34 patients were screened, 5 met the inclusion and exclusion criteria and agreed to participate. Two patients were randomized to Group A. One patient received 30 sessions of HBOT. One patient absconded after 26 sessions of HBOT. Three patients were randomized to Group B and received 40 sessions of sham treatment. All 3 control patients elected to cross over: two patients completed 40 sessions of HBOT, one stopped at 24 sessions due to an unrelated medical condition (critical limb ischemia). No serious adverse events occurred. At 14 months follow-up after HBOT, 3 patients showed improvement in SOMALENT and EPIC scores. One patient with a vesicovaginal fistula showed complete radiographic resolution at 14 months follow-up. In total, 13 patients have been recruited internationally.

Conclusion: HBOT remains a treatment option for refractory late radiation cystitis. The evidence presented is inconclusive due to the low number of patients, but the ongoing multicenter trial is expected to provide conclusive evidence.

Reference:

Smit SG, Heyns CF. Management of radiation cystitis. *Nat Rev Urol.* 2010;7:206-214.