

Chronic Radiation Cystitis and Effect of Hyperbaric Oxygen Therapy on Patient Reported Outcomes and Urine Inflammatory Biomarkers

NCT07368647

Status RECRUITING
Sponsor Rachel A. Moses
Enrollment 100 participants

Key Eligibility Criteria

Inclusion (11)

- Cohort 1
 - At least 18 years of age
 - Post pelvic radiation carrying the diagnosis of moderate to severe radiation cystitis and recurrent macroscopic hematuria in the absence of infection or urothelial malignancy. The diagnosis of moderate to severe (Radiation Therapy Oncology Group (RTOG) grade 2, 3-4) RC will be made by board-certified, reconstructive Urologists routinely managing radiation cystitis patients in their practices (RM /WB,III) or co-investigator (JB) using Appendix B and confirmed with cystoscopy and negative urine cytology and/or bladder biopsy to rule out malignancy (which is standard of care of work up of hematuria as defined by the American Urology Association)⁴⁵ once all other pathologies for gross hematuria have been excluded (including infection, malignancy, etc).
 - Scheduled to, or currently undergoing (initiated within the past 7 days), HBOT as part of standard of care therapy for radiation cystitis Cohort 2 HBOT controls
 - At least 18 years of age
- ... and 6 more (see full listing online)

Exclusion (6)

- All Cohorts
 - Pregnant or lactating (females will be asked if there is any chance they could be pregnant).
 - Uncompensated heart failure, uncompensated fluid overload, or uncompensated myocardial infarction preventing therapeutic HBOT
 - A history of: uncontrolled seizure disorder, active urinary tract infection, active Grave's disease, cystic fibrosis, sickle cell anemia, known HIV, or any autoimmune disease not in remission that requires active systemic steroid therapy or immune modulating medications.
 - Refusal to sign IRB approved informed consent document
- ... and 1 more (see full listing online)

Locations (1 total)

Dartmouth-Hitchcock Medical Center, Lebanon, New Hampshire, United States

<https://clinicaltrials.gov/study/NCT07368647>

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