

# Hyperbaric Oxygen Radiation Tissue Injury Study - III (Radiation cystitis)

<b>Submission date</b> 16/09/2008	<b>Recruitment status</b> Stopped	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 12/11/2008	<b>Overall study status</b> Stopped	<input type="checkbox"/> Protocol
<b>Last Edited</b> 18/01/2019	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**ClinicalTrials.gov (NCT)**  
NCT00134628

**Protocol serial number**  
N/A

## Study information

**Scientific Title**

Hyperbaric oxygen treatment of chronic refractory radiation proctitis: a randomized and controlled double-blind crossover trial with long-term follow-up

## **Acronym**

HORTIS - III

## **Study objectives**

The principle objective of this research is to more precisely determine the degree of benefit that hyperbaric oxygen therapy affords in the treatment of late radiation tissue injury.

The study has eight components. Seven involve evaluation of established radionecrosis at varying anatomic sites (mandible, larynx, skin, bladder, rectum, colon, and gynecology [GYN]). The eighth will investigate the potential of hyperbaric oxygen therapy to prophylax against late radiation tissue injury. This third study HORTIS-III will focus on patients with radiation cystitis.

This study will also generate more precise "Benchmarking" data as to the complications associated with hyperbaric exposure, including incidence and degree of morbidity.

Overview of the study can be found at: [http://www.baromedicalresearch.org/pdf/HORTIS\\_Overview.pdf](http://www.baromedicalresearch.org/pdf/HORTIS_Overview.pdf)

All HORTIS trials that have been registered with ISRCTN can be found at: <http://www.controlled-trials.com/isrctn/search.html?srch=HORTIS&sort=3&dir=desc&max=10>

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

The study was approved by the Palmetto Health, Richland IRB in 2002 (ref: 2002-17).

## **Study design**

Double-blind randomised placebo-controlled multi-centre trial, with cross-over option

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Radiation cystitis

## **Interventions**

Patients will be initially randomized to receive either oxygen at 2.0 atmospheres absolute (ATA), or air at 1.0 ATA.

The therapeutic algorithm is personalized to each patient's degree of response at specific points during their course of hyperbaric exposure. The total number of exposures will vary from between 20 and 40.

Following a 30-day observation/"wash out" period, the allocation assignment will be opened. Patients randomized to the 1.0 ATA air group will be offered the opportunity to cross-over to the 2.0 ATA oxygen arm. The offer is mandatory, not so the requirement of the patient to cross-over. A therapeutic algorithm identical to the first randomization will be undertaken during any subsequent cross-over phase.

### **Intervention Type**

Other

### **Phase**

Not Specified

### **Primary outcome(s)**

The following will be assessed at pre-treatment, 3 and 6 months, 1, 2, 3, 4 and 5 years post-treatment:

1. Subjective Objective Signs Management and Analysis/Late Effect of Normal Tissue (SOMA /LENT) scores
2. Clinical evaluation

### **Key secondary outcome(s)**

Quality of Life, assessed by the Expanded Prostate Cancer Index Composite (EPIC) questionnaire at pre-treatment, 3 and 6 months, 1, 2, 3, 4 and 5 years post-treatment.

### **Completion date**

21/07/2012

### **Reason abandoned (if study stopped)**

Lack of funding/sponsorship

## **Eligibility**

### **Key inclusion criteria**

1. Both males and females between the ages of 18 and 70 years
2. Patients whose cancer treatment included radiotherapy and who have developed late radiation tissue injury, manifesting as one or more of the diagnostic criteria listed below:
  - 2.1. Endarteritis
  - 2.2. Hypocellularity
  - 2.3. Hypovascularity
  - 2.4. Vascular congestion
  - 2.5. Haemorrhage
  - 2.6. Necrosis
  - 2.7. Oedema
  - 2.8. Telangiectasis
  - 2.9. Urgency
  - 2.10. Pain
  - 2.11. Fistula
  - 2.12. Erythema
  - 2.13. Contracted bladder

- 2.14. Dysplasia
- 2.15. Vascularity ulceration
- 2.16. Tissue hypoxia

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Reactive airway disease
2. Radiographic evidence of pulmonary blebs or bullae
3. Untreated pneumothorax
4. Previously documented ejection fraction less than 35%
5. History of seizures (except childhood febrile seizures)
6. Cardiovascular instability
7. Mechanical ventilator support
8. Unable to follow simple commands
9. Not orientated to person, place, time
10. Participating as a subject in any other medical or biomedical research project (if previously involved as a subject, sufficient time must have elapsed to permit "wash out" of any investigational agent)

**Date of first enrolment**

21/07/2003

**Date of final enrolment**

21/07/2012

**Locations****Countries of recruitment**

Australia

Mexico

South Africa

Türkiye

United States of America

**Study participating centre**  
**Baromedical Research Foundation**  
Columbia  
United States of America  
29203

## Sponsor information

**Organisation**  
Baromedical Research Foundation (USA)

## Funder(s)

**Funder type**  
Industry

**Funder Name**  
National Baromedical Services, Inc (USA)

**Funder Name**  
The Lotte and John Hecht Memorial Foundation (Canada)

## Results and Publications

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**  
Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results of one treatment arm	01/09/2008	18/01/2019	Yes	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes