

# Hyperbaric Oxygen Radiation Tissue Injury Study - IV (Radiation proctitis)

<b>Submission date</b> 08/04/2005	<b>Recruitment status</b> Stopped	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 18/05/2005	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 25/01/2019	<b>Condition category</b> Cancer	<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

## Study information

**Scientific Title**  
Hyperbaric Oxygen Radiation Tissue Injury Study - IV (Radiation proctitis)

**Acronym**  
HORTIS - IV

**Study objectives**

Radiation of prostate, urological and gynecological cancers frequently places the rectum within the radiation portal. Resulting tissue injury will manifest months to years later in a not insignificant percentage of patients. Symptoms include pain, bleeding, bowel dysfunction, stricture, oedema, erythema, tissue friability, ulceration, necrosis and fistulae. Therapeutic approaches include topical agents, transfusions, careful diet, pain control, laser coagulation and surgical resection.

Clinical experience and clinical evidence of a beneficial role of hyperbaric oxygen are generally encouraging but no prospective systematic analysis of outcomes has been reported. HORTIS IV represents the first randomised controlled trial to investigate hyperbaric medicine's therapeutic role at this anatomic site.

**Aim:**

To determine the effectiveness of hyperbaric oxygen (HBO) therapy as either a prophylaxis against, or treatment of, late radiation tissue injury (RTI).

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)**

Not provided at time of registration

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

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

Radiation Proctitis

**Interventions**

Patients enrolled in the trial have undergone (and failed to respond to) standard care for a period of not less than 90 days. These patients are included in the trial and assigned to either an active arm (hyperbaric oxygen therapy) or a placebo arm. Patients may require some kind of standard care while in the trial to overcome acute exigencies (e.g., blood transfusion, surgical cauterisation, etc.).

This trial has been closed to further patient recruitment. The protocol can be found at [http://www.baromedicalresearch.org/pdf/HORTISIV\\_Protocol.pdf](http://www.baromedicalresearch.org/pdf/HORTISIV_Protocol.pdf).

**Intervention Type**

Other

## **Phase**

Not Specified

## **Primary outcome(s)**

SOMA (subjective, objective, management, analytic) scale used to determine late effects to normal tissue (LENT) score. Time frame: pre-treatment, post-treatment (HBO and placebo) and at follow ups at 3 months, 6 months, and 1 year through 5 years.

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

Clinical assessment using one of the following criteria:

1. Healed
2. Modestly improved (less than 50% lesion resolution)
3. Not improved
4. Other (e.g., lesion recurrence, lesion size progression)
5. Significant improvement (greater than 50% lesion resolution)

Time frame: post-treatment (HBO and placebo) and at follow-ups at 3 and 6 months, and 1 year through 5 years

## **Completion date**

12/02/2005

## **Eligibility**

### **Key inclusion criteria**

Patients whose cancer treatment included radiotherapy and who have developed late radiation tissue injury, manifesting as one or more of the following diagnostic criteria:

1. Endarteritis
2. Hypocellularity
3. Hypovascularity
4. Mucosal thickening
5. Diarrhoea
6. Vomiting
7. Cramping
8. Tenesmus
9. Obstruction
10. Constipation
11. Stricture
12. Perforation
13. Pain
14. Fistula
15. Haemorrhage
16. Obstipation
17. Wall changes
18. Tissue hypoxia
19. Ulceration

### **Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

Patients, who are pregnant or have any of the following illnesses, conditions or requirement:

1. Pregnancy
2. Reactive airway disease
3. Radiographic evidence of pulmonary blebs or bullae
4. Untreated pneumothorax
5. Previously documented ejection fraction less than 35%
6. History of seizures - except childhood febrile seizures
7. Cardiovascular instability
8. Mechanical ventilator support
9. Unable to follow simple commands
10. Not orientated to person, place, time
11. 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**

01/01/2001

**Date of final enrolment**

12/02/2005

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

Australia

Mexico

South Africa

Türkiye

United States of America

**Study participating centre**

**5 Richland Medical Park**  
Columbia  
United States of America  
29203

## **Sponsor information**

**Organisation**  
Baromedical Research Foundation (USA)

## **Funder(s)**

**Funder type**  
Charity

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

**Funder Name**  
The Gustavus and Louise Pfeiffer Research Foundation (USA)

**Funder Name**  
Atlantic Hyperbaric Associates (USA)

**Funder Name**  
Mercy Health Partners (USA)

**Funder Name**  
Hyperbaric Physician Services (USA)

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

# 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="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes