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

Submission date	Recruitment status	[_] Prospectively registered
16/09/2008	Stopped	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/11/2008	Stopped	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/01/2019	Urological and Genital Diseases	[_] 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

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?
Results article	results of one treatment arm	01/09/2008	18/01/2019	Yes	No
Participant information sheet	Participant information sheet Study website	11/11/2025	11/11/2025	No	Yes

Study website	11/11/2025	11/11/2025	No	Yes