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

Submission date 08/04/2005	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 18/05/2005	**Overall study status** Stopped	
Last Edited 25/01/2019	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.baromedicalresearch.org/radiation_proctitis.asp

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00134628

Secondary identifying numbers
N/A

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

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)

Treatment

Participant information sheet

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 exigiencies (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.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
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.

Secondary outcome measures
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

Overall study start date
01/01/2001

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
150

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)

Sponsor details
5 Richland Medical Park
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Sponsor type
Charity

Website
http://baromedicalresearch.org/

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration