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

Submission date 08/04/2005	Recruitment status Stopped	Prospectively registered
08/04/2003	Stopped	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
18/05/2005	Stopped	Results
Last Edited	Condition category	Individual participant data
25/01/2019	Cancer	Record updated in last year

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

Contact name

Mr Richard Clarke

Contact details

5 Richland Medical Park Columbia United States of America 29203

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)

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 Columbia United States of America 29203

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