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Hyperbaric Oxygen Radiation Tissue Injury Study - I (Soft tissue radionecrosis)

Submission date	Recruitment status	[_] Prospectively registered
16/09/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
17/10/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
17/01/2019	Cancer	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.baromedicalresearch.org/soft_tissue_radionecrosis.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 - I (Soft tissue radionecrosis)

Acronym
HORTIS - I

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 gynaecology [GYN]). The eighth will investigate the potential of hyperbaric oxygen therapy to prophylax against late radiation tissue injury. This first study HORTIS-I will focus on patients with soft tissue radionecrosis.

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

All HORTIS trials that have been registered with ISRCTN can be found at: https://www.isrctn.com/search?q=HORTIS

Ethics approval required
Old ethics approval format

Ethics approval(s)
This 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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Soft tissue radionecrosis

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 measure
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

Secondary outcome measures
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.

Overall study start date
23/02/2001

Completion date
21/07/2012

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. Ulceration
2.6. Dehiscence
2.7. Ischemia
2.8. Necrosis
2.9. Skin graft failure
2.10. Skin flap failure
2.11. Spontaneous breakdown
2.12. Pain
2.13. Delayed healing
2.14. Local Tissue Hypoxia

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

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 (with the exception of those patients who are immediately [1-5 days] post-operative)
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
23/02/2001

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
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Sponsor information

Organisation
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Sponsor type
Research organisation

Website
http://www.baromedicalresearch.org

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2008	17/01/2019	Yes	No