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

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

#### 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

**Contact name** Mr Richard Clarke

#### **Contact details**

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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 crossover. 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:

Subjective Objective Signs Management and Analysis/Late Effect of Normal Tissue (SOMA /LENT) scores
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 United States of America 29203

### Sponsor information

**Organisation** Baromedical Research Foundation (USA)

**Sponsor details** 5 Richland Medical Park Columbia United States of America 29203 +1 803 434 7101 ktaylor@baromedicalresearch.org

**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?
<u>Results article</u>	results	01/09/2008	17/01/2019	Yes	No