

# A phase I clinical trial of Hyperbaric Oxygen combined with radiation and chemotherapy for locally advanced squamous cell carcinoma of the head and neck

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|-------------------|----------------------|--|
| Submission date   | Recruitment status   | <input type="checkbox"/> Prospectively registered    |
| 11/05/2007        | No longer recruiting | <input type="checkbox"/> Protocol                    |
| Registration date | Overall study status | <input type="checkbox"/> Statistical analysis plan   |
| 22/05/2007        | Completed            | <input checked="" type="checkbox"/> Results          |
| Last Edited       | Condition category   | <input type="checkbox"/> Individual participant data |
| 01/02/2019        | Cancer               |  |

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Mr Richard Clarke

### Contact details

5 Richland Medical Park  
Department of Hyperbaric Medicine  
Columbia  
South Carolina  
United States of America  
29203  
-  
dick.clarke@palmettohealth.org

## Additional identifiers

### ClinicalTrials.gov (NCT)

NCT00474825

### Protocol serial number

BRF 06-01

# Study information

## Scientific Title

Hyperbaric oxygen as a radiation sensitizer for locally advanced squamous cell carcinoma of the head and neck: A phase I dose-escalation study.

## Acronym

HBO-XRT Phase I

## Study objectives

This research is carried out as we do not know the best treatment for advanced squamous cell carcinoma of the head and neck. These cancers have been treated with a combination of surgery, radiation and chemotherapy in varying combination. When the tumor is inoperable, radiation therapy is used with or without chemotherapy in the hope of curing the tumor.

Recently, it has become recognized as generalized knowledge that cancer cells are hypoxic (low oxygen concentration). Because of the low oxygen concentrations, many cancer treatments have not been successful. The theory behind this study is to give oxygen to patients prior to chemotherapy and radiation in hope of generating greater results in killing cancer cells.

This study has two main objectives:

1. To determine patient tolerance to increasing dose of HyperBaric Oxygen (HBO) therapy
2. To determine the feasibility of treatment delivery and acute toxicities associated with each regimen

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

1. Norfolk General Hospital / Eastern Virginia Medical School - Office of Research Subjects Protections Institutional Review Board (IRB), approved on 18 April 2007. Ref: 07-02-FB-0045

IRB review ongoing for three centers as of 22/05/2007:

2. The Mayo Clinic (Minnesota, USA)
3. Dartmouth-Hitchcock Medical Center (New Hampshire, USA)
4. Palmetto Health Richland (South Carolina, USA)

## Study design

Multi-center, non-randomized clinical trial.

## Primary study design

Interventional

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Locally advanced squamous cell carcinoma of the head and neck.

## Interventions

HBO therapy in conjunction with standard care (chemotherapy and radiation therapy). Each HBO session will last for 30 minutes. There are 3 arms in this intervention, each with a different HBO dosage per week.

The first 3 patients will receive HBO twice a week (Monday and Friday) for 7 weeks (Arm 1). If no adverse event is reported, another set of 3 patients will receive HBO three times a week (Monday, Wednesday and Friday) for 7 weeks (Arm 2). Again, if no adverse event is observed, a final set of 3 patients will receive HBO five times a week (Monday through Friday) for 7 weeks (Arm 3).

In case an adverse event is reported in any of the three arms, another set of 3 patients will be randomized in the same arm to see if the events are repeated.

### **Intervention Type**

Drug

### **Phase**

Phase I

### **Drug/device/biological/vaccine name(s)**

hyperbaric oxygen

### **Primary outcome(s)**

Patient tolerance to each arm of the trial during the treatment, determined by the occurrence of Grade IV acute toxicity using the NCI Common Terminology Criteria for Adverse Events (CTCAE) v3.0.

### **Key secondary outcome(s)**

1. Feasibility of treatment delivery
2. Acute toxicities associated with each regimen
3. Quality of life, assessed by the following:
  - 3.1. The Functional Assessment of Cancer Therapy (FACT) - Head and Neck Cancer, assessed at pre-treatment and then at 6 months, 1 year and 2 years after completing treatment
  - 3.2. The Performance Status Scale (PSS) for Head and Neck cancer, assessed at pre-treatment, during the last two weeks of treatment, and then at 3 months, 1 year and 2 years after completing treatment

### **Completion date**

02/01/2008

## **Eligibility**

### **Key inclusion criteria**

1. Histological proof (from the primary lesion and/or lymph nodes) of squamous cell carcinoma of the oral cavity, oropharynx, or hypopharynx
2. Stage III or IV, M0 squamous cell carcinoma
3. Life expectancy of at least 6 months and a Karnofsky performance status of  $\geq 70$
4. Age  $\geq 18$  years and  $\leq 70$  years
5. Patients must sign a study-specific informed consent form

### **Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Histology other squamous cell carcinoma
2. Evidence of metastasis (below the clavicle or distant) by clinical or radiographic means
3. Previous complete resection of the primary tumor
4. Previous chemotherapy (Bleomycin) for head and neck cancer or radiotherapy to the head and neck
5. Patients with simultaneous primaries
6. Pregnancy
7. Pulmonary pathologies (risk of decompression-induced pulmonary barotrauma):
  - 7.1. Current, untreated pneumothorax
  - 7.2. History of pneumothorax
  - 7.3. History of intrathoracic surgery
  - 7.4. History of pulmonary blebs or bullous lung disease
  - 7.5. Associated with CO<sub>2</sub> retention
  - 7.6. Poorly controlled or associated with acute bronchospasm
8. Clinically significant heart diseases:
  - 8.1. Significant ventricular arrhythmia requiring medication with antiarrhythmics
  - 8.2. Symptomatic coronary artery disease (angina)
  - 8.3. Myocardial infarction within the last 6 months
  - 8.4. Second or third degree heart block or bundle branch block or clinically significant conduction system abnormality
9. Where the hyperbaric physician deems the patient to have an unacceptable risk for hyperbaric treatments
10. Claustrophobia

**Date of first enrolment**

07/01/2007

**Date of final enrolment**

02/01/2008

## Locations

**Countries of recruitment**

United States of America

**Study participating centre**  
5 Richland Medical Park  
South Carolina  
United States of America  
29203

## Sponsor information

### Organisation

The Baromedical Research Foundation (USA)

## Funder(s)

### Funder type

Other

### Funder Name

The Baromedical Research Foundation (USA)

## 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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 20/05/2010   | 01/02/2019 | Yes            | No              |