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

Submission date 11/05/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 22/05/2007	**Overall study status** Completed	
Last Edited 01/02/2019	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00474825

Secondary identifying numbers
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 Proctections 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. Darthmouth-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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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.

Secondary outcome measures
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

Overall study start date
07/01/2007

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 ≥ 70
4. Age ≥ 18 years and ≤ 70 years
5. Patients must sign a study-specific informed consent form

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
9 to 18

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 CO2 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
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Sponsor information

Organisation
The Baromedical Research Foundation (USA)

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Sponsor type
Other

Funder(s)

Funder type
Other

Funder Name
The Baromedical Research Foundation (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	20/05/2010	01/02/2019	Yes	No