

# Hyperbaric Oxygen for the Prevention of OsteoradioNecrosis

<b>Submission date</b> 21/05/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 13/06/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 04/06/2026	<b>Condition category</b> Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

<http://www.cancerhelp.org.uk/trials/a-study-looking-at-a-treatment-to-prevent-jaw-bone-damage-in-head-and-neck-cancer>

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

### Protocol serial number

2

## Study information

### Scientific Title

A randomised controlled trial of hyperbaric oxygen to prevent osteoradionecrosis of the irradiated mandible

## **Acronym**

HOPON

## **Study objectives**

The aim of this study is to determine the benefit of hyperbaric oxygen (HBO) in the prevention of osteoradionecrosis (ORN) subsequent to a surgical procedure in the "at risk" irradiated mandible. This study is designed as a randomised control multi-centre feasibility study.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Central Manchester Research Ethics Committee on 28/04/2008 (ref: 08/H1008/32)

## **Primary study design**

Interventional

## **Study design**

Multicentre randomised controlled trial

## **Study type(s)**

Prevention

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

Osteoradionecrosis subsequent to a surgical procedure in an irradiated mandible

## **Interventions**

Arm 1: Standard management:

1. Pre- and post-operative chlorohexidine 1 mouthwash 0.2% - use 10 ml (i.e. one capful) washed around the mouth for around 1 minute and spat out, three times daily for 5 days post-operatively.

1.1. In case of chlorohexidine allergy use warm salt mouthwash at 1 teaspoon per cup of warm water.

2. Oral antibiotics: amoxicillin 3 g oral 1 hour pre-operatively (or 1 g intravenously), and 250 mg three times a day (tds) x 5 days post-operatively

2.1. In penicillin allergy: Orally either 600 mg tablet, or same dose of 75 mg/5 ml suspension if tablets not tolerated, 1 hour pre-operatively or intravenously 600 mg at time of surgery, and 200 mg metronidazole (patients should be warned of interaction between alcohol and metronidazole) tds x 5 days post-operatively

Arm 2: Standard management plus HBO

Patients will undergo 20 HBO treatments prior to surgery followed by a further 10 HBO treatments. HBO will comply with dive table RN66. For each HBO treatment, patients are compressed to 2.4 ata while sitting in an appropriate British Hyperbaric Association recognised hyperbaric chamber. Patients breathe 100% oxygen at pressure via a transparent hood. The total time at 2.4 ata is 90 minutes. During the final 10 minutes of oxygen breathing, the chamber is depressurised to ambient atmospheric pressure at a linear rate (14.3 kpa/min).

3. All participants will be operated with a minimally traumatic surgical technique after the standard management with or without HBO.

## **Intervention Type**

Other

## **Primary outcome(s)**

Mucosal healing and/or the presence of necrotic bone at 6 months following surgery, measured by the following:

1. Clinical assessment in centre
2. Clinical photograph with in-photograph ruler
3. Radiographic using orthopantomogram (OPT)

The primary outcome will be based on a blinded assessment of anonymised clinical photograph and radiograph by a central committee consisting of experienced clinicians in the field.

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

1. Mucosal healing at 3 months following surgery (measured as at 6 months following surgery)
2. Severity of cases of diagnosed osteoradionecrosis, with clinical and radiographic recordings of severity made according to the following:
  - 2.1. Grade I: ORN confined to alveolar bone
  - 2.2. Grade II: ORN limited to the alveolar bone and/or mandible above the level of inferior alveolar canal
  - 2.3. Grade III: ORN involving the mandible below the level of inferior alveolar canal and ORN with a skin fistula and/or pathologic fracture
3. Pain: patient questionnaire at 3 and 6 months
4. Quality of life (QoL): prior to randomisation but following consent, and at 3 and 6 months (as determined by a modified University of Washington)
5. Head and Neck QoL questionnaire (modified) at baseline, 3 and 6 months
6. Adverse events in HBO arm related to hyperbaric oxygen treatment, monitored throughout trial
7. Admissions, operations, complications (e.g. major bleeding, sepsis), monitored throughout trial
8. Mortality. Patients will be followed up until death or 6 months.
9. Implant retention (where appropriate) and outcomes of ORN (where appropriate) at 12 and 24 months following surgery

## **Completion date**

31/05/2014

## **Eligibility**

### **Key inclusion criteria**

1. Both males and females, age >18 years
2. Prior history of external beam radiotherapy (dose >50 Gy) to mandible or prior history of brachytherapy with equivalent radiation dose as above
3. No evidence of cancer recurrence
4. Condition requiring surgery to mandible (commonest examples but not limited to: dental extraction, implant placement, surgical tooth, cyst or osteosynthesis plate removal)
5. Patient has read and understood information leaflet and is willing to be randomised
6. Patient competent to consent and psychologically/ physically fit for HBO

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

18 Years

**Upper age limit**

120 Years

**Sex**

All

**Total final enrolment**

0

**Key exclusion criteria**

1. Known contraindications to HBO:

1.1. Lung disease: Severe chronic obstructive airways disease; bullous lung disease, acute or chronic pulmonary infection; uncontrolled asthma, untreated pneumothorax

12. Middle ear disease (such as previous middle ear operations, eustachian tube dysfunction or recurrent attacks of vertigo) that proves refractory to simple interventions such as grommet insertion

2. Prior hyperbaric oxygen therapy

3. Prior diagnosis of osteoradionecrosis of the mandible

4. Previous surgery for osteoradionecrosis

5. Any history of systemic bisphosphonate therapy, pentoxifylline or tocopherol

6. Pregnancy

**Date of first enrolment**

01/06/2008

**Date of final enrolment**

31/05/2014

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**

## Regional Maxillofacial Unit

-  
Liverpool  
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## Sponsor information

### Organisation

University of Liverpool (UK)

### ROR

<https://ror.org/04xs57h96>

## Funder(s)

### Funder type

Charity

### Funder Name

Cancer Research UK (ref: C23033/A9397)

### Alternative Name(s)

CR\_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

### Funding Body Type

Private sector organisation

### Funding Body Subtype

Other non-profit organizations

### Location

United Kingdom

## Results and Publications

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not expected to be made available

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Plain English results</a>			04/06/2026	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes