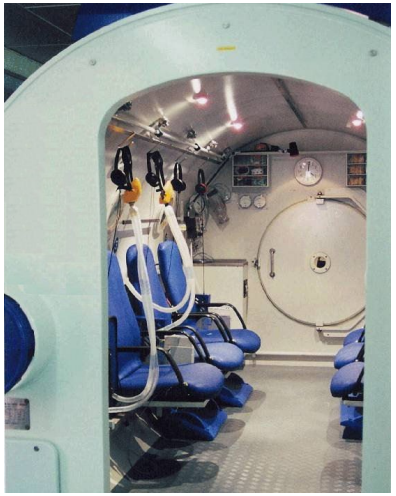
Sites involved will be awarded £200 for each patient who completes the trial. For more information please contact Mr. Matthew Bickerstaff (Trial Coordinator) or Mr. Richard Shaw (Chief Investigator) (please see contact details on back)

Study Objective

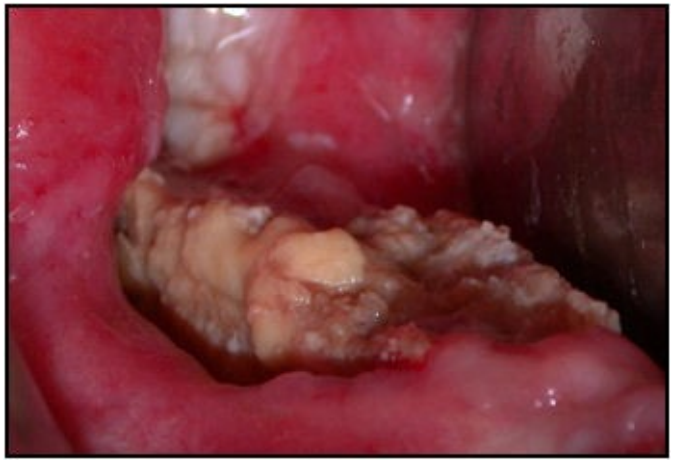
The main objective of the trial is to determine the benefit of HBO in the prevention of osteoradionecrosis (ORN) subsequent to a surgical procedure in the "at risk" irradiated mandible.



Experimental arm is Standard management plus HBO: Patients will undergo 20 HBO treatments prior to surgery followed by a further 10 daily HBO treatments. For details of the standard management please visit the HOPON webpage at: http://www.lctu.org.uk/trial/hopon.html

Background

HOPON has been developed by members of the Head and Neck NCRI sub-groups (Richard Shaw, Sheila Fisher, Chris Nutting, Peter Brennan, Christopher Butterworth) and through discussion with BAHNO, RCSEng study day, BAOMS and in consultation with members of the British Hyperbaric Association.



Outcomes

Primary Outcome:

Mucosal healing at 3 months following surgery

Secondary Outcomes include mucosal healing, severity of ORN, pain, quality of life, adverse events and mortality. For the full list of secondary outcomes please visit:

http://www.lctu.org.uk/trial/hopon.html

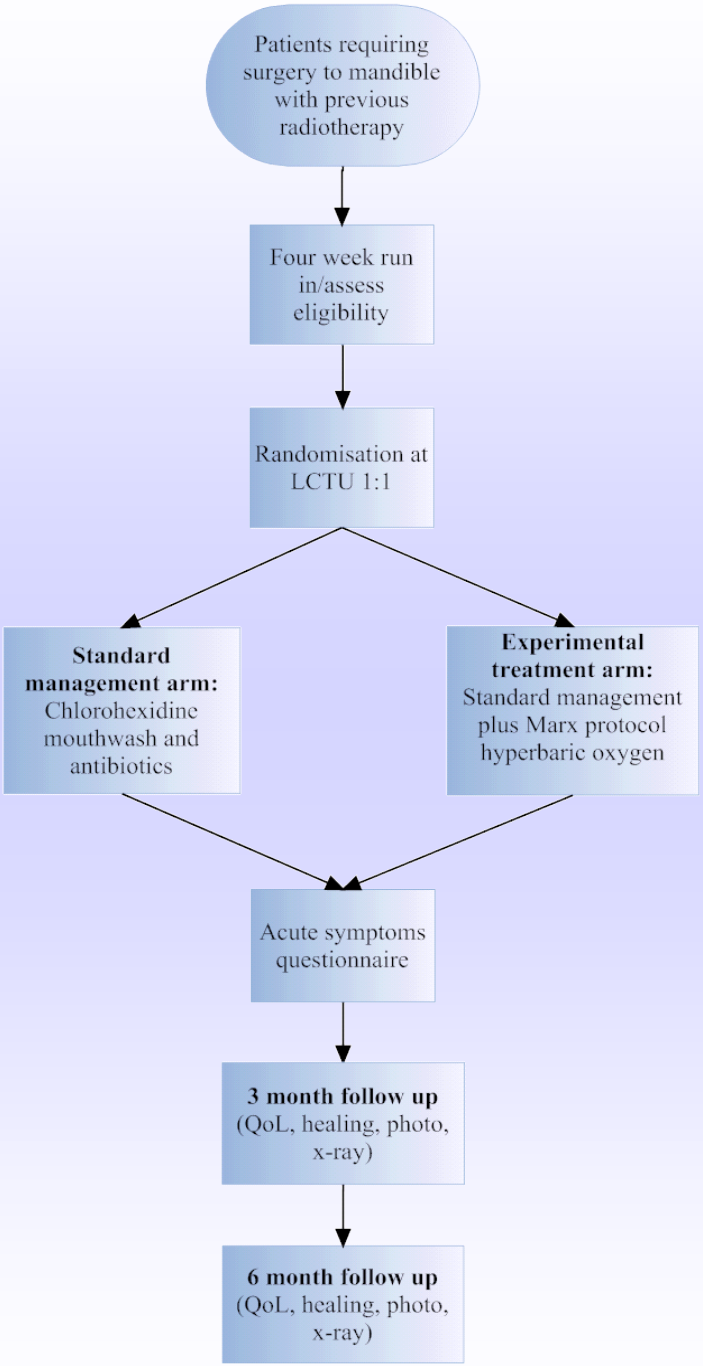
Inclusion Criteria

- Condition requiring surgery to the posterior mandible e.g. dental extraction, "surgical", implant placement
- Prior history of external beam radiotherapy (dose > 50Gy) to mandible or prior history of brachytherapy with equivalent radiation dose as above.
- Age > 18 years
- No evidence of cancer recurrence

Exclusion Criteria

- Known contraindications to HBO
  - Lung disease: Chronic obstructive airways disease; bullous lung disease, acute or chronic pulmonary infection; uncontrolled asthma, untreated pneumothorax
  - 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
- Prior hyperbaric oxygen therapy
- Prior diagnosis of ORN of the mandible
- Previous surgery for ORN
- Any history of systemic bisphosphonate therapy, pentoxyphylline or tocopherol.
- Pregnancy

Trial Design



The LCTU

The Liverpool Cancer Trials Unit works closely with Cancer Research UK in the clinical research of new and existing products for the treatment of cancer, easing suffering and improving the quality of life for cancer patients.

Further Information

This trial is funded by Cancer Research UK, through FSC. The trial will open in May 2008

Trial Coordinator

Matthew Bickerstaff

email: oasis@liv.ac.uk

Chief Investigator

Mr Richard Shaw

email: richard.shaw@liv.ac.uk

For more information about head and neck cancer or current trials running within the Liverpool Cancer Trials Unit, please email:

lctu@liverpool.ac.uk

Or visit the LCTU website:

www.lctu.org.uk

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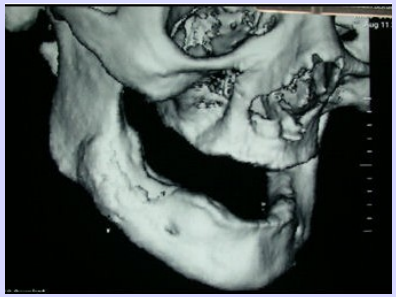
HOPON



Hyperbaric Oxygen for the Prevention of Osteoradionecrosis

NCRI National Cancer Research Institute