



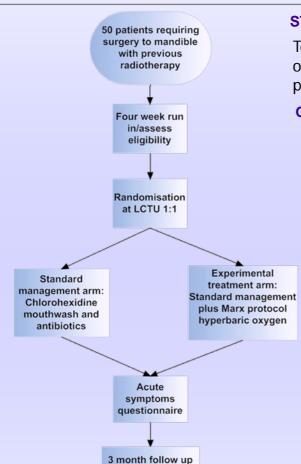


Hyperbaric Oxygen for the Prevention of Osteoradionecrosis

BACKGROUND

- Osteoradionecrosis (ORN) is a complication of radiotherapy for head and neck cancer
- ORN is where irradiated bone undergoes necrosis and becomes exposed through the soft tissues
- The morbidity and mortality of osteoradionecrosis is significant
- Treatment outcomes are often unsatisfactory
- There have only been limited studies of prophylactic HBO





(QoL, healing, photo, x-ray)

6 month follow up

(QoL, healing,

photo, x-ray)

STUDY OBJECTIVE

To determine the benefit of HBO in the prevention of osteoradionecrosis (ORN) subsequent to a surgical procedure in the "at risk" irradiated mandible

OUTCOMES

Primary Outcome:

Mucosal healing at 3 months following surgery

Secondary Outcomes:

- Mucosal healing at 3 months following surgery
- Severity of cases of diagnosed osteoradionecrosis
- Pain: patient questionnaire at 3 and 6 months
- Radiographic appearance: orthopantomogram (OPT) at 3 and 6 months
- Clinical photographs at 3 and 6 months
- Quality of life (QoL): at 3 and 6 months
- Adverse events in HBO arm related to hbo treatment
- Admissions, operations, complications
- Mortality
- Implant retention (where appropriate) and outcomes of ORN (where appropriate) at 12 and 24 months following surgery

EXPERIMENTAL ARM

Standard management plus HBO: Patients will undergo 20 HBO treatments prior to surgery followed by a further 10 daily HBO treatments.

INCLUSION CRITERIA

- Age > 18 years
- Prior history of external beam radiotherapy (dose > 50Gy) to mandible or prior history of brachytherapy with equivalent radiation dose as above.
- No evidence of cancer recurrence
- Condition requiring surgery to mandible



FOR FURTHER DETAILS PLEASE CONTACT