ISRCTN25123615 https://doi.org/10.1186/ISRCTN25123615

Prevention of radiotherapy side-effects by early hyperbaric oxygen administration

Submission date 04/04/2006	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 04/04/2006	**Overall study status** Completed	
Last Edited 18/09/2008	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof P.C. Levendag

Contact details
Erasmus Medical Centre
Department of Radiotherapy
Groenehilledijk 301
Rotterdam
Netherlands
3075 EA
p.levendag@erasmusmc.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MEC 2005-318; NTR617

Study information

Scientific Title

Study objectives
To prevent radiotherapy side-effects with early hyperbaric oxygen administration.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Randomised, active controlled, parallel group 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
Nasopharyngeal cancer, oropharyngeal cancer

Interventions
Randomisation of hyperbaric oxygen (one group with and one group without). Treatment consists of 30 sessions of 2 hours a day.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Xerostomia
2. Mucositis
3. Trismus

Secondary outcome measures

1. Tumour control
2. Quality of life

Overall study start date
06/02/2006

Completion date
06/02/2009

Eligibility

Key inclusion criteria
1. Curative intent
2. Presence of oropharynx and nasopharynx tumours

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
180

Key exclusion criteria
Palliative treatment

Date of first enrolment
06/02/2006

Date of final enrolment
06/02/2009

Locations

Countries of recruitment
Netherlands

Study participating centre
Erasmus Medical Centre
Rotterdam
Netherlands
3075 EA

Sponsor information

Organisation
Erasmus Medical Centre (The Netherlands)

Sponsor details
P.O. Box 2040
Rotterdam
Netherlands
3000 CA

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Erasmus Medical Centre (The Netherlands)

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