

Prevention of radiotherapy side-effects by early hyperbaric oxygen administration

Submission date 04/04/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 04/04/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 18/09/2008	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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

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