

Double-blind randomized placebo-controlled clinical trial for treatment of breast symptoms with hyperbaric oxygen after breast-preserving operation and radiation

Submission date 09/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 28/10/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 24/07/2014	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

Study information

Scientific Title

Acronym

O2-Studie

Study objectives

Comparison of hyperbaric oxygen and placebo.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Status after operation and radiation for mammary cancer.

Interventions

Hyperbaric oxygen versus placebo.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Lent-Soma score (4 months).

Secondary outcome measures

1. Lent-Soma score (final)
2. EORTC LQ30 plus breast module (4 months, final)
3. Dermal thickness (4 months)

Overall study start date

12/11/2003

Completion date

31/12/2007

Eligibility**Key inclusion criteria**

1. Invasive mammary cancer
2. Breast-preserving treatment and post-radiation (finalized at least 12 months before)
3. Lent-Soma score ≥ 8 and or pain grade III
4. Age ≥ 18
5. Informed consent
6. Last chemotherapy before at least 6 weeks
7. Normal electrocardiogram (ECG)
8. Normal thorax X-ray
9. Normal lung function
10. Normal ear drum findings and tubal patency

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

20

Key exclusion criteria

1. Untreated valvular pneumothorax
2. Relevant obstructive ventilation disorders
3. Decompensated heart insufficiency
4. Metastases
5. Pretreatment with bleomycin
6. Relevant intrapulmonal focal findings
7. Relevant thoracic injuries
8. Pregnancy
9. Relevant psychiatric diseases

- 10. Non-controllable claustrophobic reactions
- 11. Spastic disorders
- 12. Acute febrile diseases
- 13. Drug and alcohol abuse

Date of first enrolment

12/11/2003

Date of final enrolment

31/12/2007

Locations

Countries of recruitment

Germany

Study participating centre

Klinik für Strahlentherapie und Radioonkologie

Düsseldorf

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Sponsor information

Organisation

Heinrich-Heine-University Düsseldorf (Germany)

Sponsor details

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Sponsor type

University/education

Website

<http://www.kksd.de>

ROR

<https://ror.org/024z2rq82>

Funder(s)

Funder type

University/education

Funder Name

Heinrich-Heine-University Dusseldorf

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