ISRCTN43727802 https://doi.org/10.1186/ISRCTN43727802

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

Registration date
28/10/2005

Last Edited
24/07/2014

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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

Protocol serial number
01S1_020

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

Study type(s)
Treatment

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(s)
Lent-Soma score (4 months).

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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
Germany
40225

Sponsor information

Organisation
Heinrich-Heine-University Düsseldorf (Germany)

ROR
https://ror.org/024z2rq82

Funder(s)

Funder type
University/education

Funder Name
Heinrich-Heine-University Dusseldorf

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration