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

### Primary study design
Interventional

### Study design
Randomised controlled trial

### 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