ISRCTN00743708 https://doi.org/10.1186/ISRCTN00743708

Randomised phase II trial of Hyperbaric Oxygen Therapy in patients with chronic arm lymphoedema after radiotherapy for early breast cancer

Submission date 08/09/2004	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 21/09/2004	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 20/01/2022	**Condition category** Circulatory System	[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.icr.ac.uk/research/research_sections/clinical_trials/clinical_trials_list/2385_disease.shtml

Contact information

Type(s)
Scientific

Contact name
Prof John Yarnold

Contact details
Institute of Cancer Research
123 Old Brompton Road
London
United Kingdom
SW7 3RP

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00077090

Secondary identifying numbers
MREC/04/4/016

Study information

Scientific Title
Randomised phase II trial of Hyperbaric Oxygen Therapy in patients with chronic arm lymphoedema after radiotherapy for early breast cancer

Acronym
HOT

Study objectives
Added 06/08/09:
The primary aim is to test the efficacy of hyperbaric oxygen (HBO) therapy in reducing arm lymphoedema in patients suffering long-term adverse effects of high dose radiotherapy for early breast cancer. The secondary aim is to test mechanisms of tissue reperfusion and healing in response to hyperbaric oxygen (HBO) therapy.

As of 06/08/09 this record has been extensively updated. All updates can be found under the relevant field with the above update date.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised active controlled parallel group 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
Chronic radiation-induced arm lymphoedema.

Interventions
Treatment group: Patients are compressed to 2.4 Atmospheres Absolute (ATA) while sitting in a multiplace hyperbaric chamber. Patients breathe 100% oxygen at pressure via a transparent hood. The total time at 2.4 ATA is 90 minutes. Each participant will receive a total of 30 pressure exposures (5 days per week for 6 weeks).

Control group: Patients continue treatment according to best standard management as defined by the trial protocol.

Intervention Type
Other

Phase
Phase II

Primary outcome measure
Added 06/08/09:
Volume of the affected limb, expressed as a percentage of the contralateral limb Volume on the day of measurement, as measured by perometer 12 months after baseline assessment

Secondary outcome measures
Added 06/08/09:
1. Patient self-assessments, using specific quality of life scale in upper limb lymphoedema and the UK SF-36 Health Survey Questionnaire, at 3, 6, 9 and 12 months after baseline assessment
2. 99Tc-nanocolloid clearance rate as measured by quantitative lymphoscintigraphy 12 months after baseline assessment
3. Extracellular water content as measured by EdemaMeter (bioimpedance measurements) 12 months after baseline assessment

Overall study start date
01/01/2006

Completion date
31/12/2008

Eligibility

Key inclusion criteria
1. Cancer patients with a past history of breast surgery +/- axillary dissection.
2. Past history of radiotherapy to the breast/chest wall +/- axilla and/or supraclavicular fossa (SCF) (at least 2 years prior to trial entry).
3. At least 15% increase in arm volume (compared to the contralateral arm).
4. Physical and psychological fitness for hyperbaric oxygen therapy.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
63

Total final enrolment
58

Key exclusion criteria
Evidence of cancer recurrence.

Date of first enrolment
01/01/2006

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Institute of Cancer Research
London
United Kingdom
SW7 3RP

Sponsor information

Organisation
The Institute of Cancer Research (UK)

Sponsor details
123 Old Brompton Road
London
United Kingdom
SW7 3RP
-
john.yarnold@icr.ac.uk

Sponsor type

Research organisation

Website
http://www.icr.ac.uk/

ROR
https://ror.org/043jzw605

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (CRUK) (UK) (C181/A4552) - research costs

Funder Name
Department of Health - excess treatment costs

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2010		Yes	No
Plain English results			20/01/2022	No	Yes