

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 21/09/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 20/01/2022	Condition category Circulatory System	<input type="checkbox"/> 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

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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