ISRCTN86894066 https://doi.org/10.1186/ISRCTN86894066

A trial looking at Hyperbaric Oxygen (HBO) Treatment for people who have long-term side effects following radiotherapy for pelvic cancer

Submission date
05/03/2008

Recruitment status
No longer recruiting

Registration date
31/03/2008

Overall study status
Completed

Last Edited
26/10/2022

Condition category
Cancer

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

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-high-pressure-oxygen-for-radiotherapy-side-effects

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT01087268

Secondary identifying numbers
N/A

Study information

Scientific Title
Randomised double-blind phase III trial of hyperbaric oxygen therapy in patients suffering long-term adverse effects of radiotherapy for pelvic cancer

Acronym
HOT II

Study objectives
Curative radiotherapy is prescribed to an increasing number (12,000 per year) of UK patients with pelvic malignancies, and more individuals are living with a significant legacy of treatment related morbidity. The UK prevalence of radiation-induced bowel morbidity causing significant impairment of physical functioning is unknown, but the US estimate is one million individuals.

The primary goal of this trial is to test the clinical benefits of high pressure oxygen therapy in restoring normal bowel function to patients suffering chronic radiation-induced gastrointestinal complications following curative radiotherapy for pelvic cancers.

On 09/10/2008 the overall trial start date was changed from 01/08/2008 to 01/11/2008.

On 21/04/2015 the overall trial end date was changed from 01/08/2011 to 01/12/2013.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Central Office for Research Ethics Committees (COREC), 23/09/2008

Study design
Multicentre double-blind randomised controlled phase III trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
http://www.royalmarsden.nhs.uk/research/clinical-trials/Documents/hot-ii-patient-information-sheet.pdf

Health condition(s) or problem(s) studied
Pelvic cancer

Interventions
Treatment group:
Patients are compressed to 2.4 atmospheres (ATA) in a hyperbaric chamber and breathe 100% oxygen at pressure following a RN66 (Royal Navy) protocol. The total time at 2.4 ATA is 90 minutes. Each participant receives 40 pressure exposures (five days per week for eight weeks).

Control group:
Patients are compressed to 1.3 ATA in a hyperbaric chamber and breathe 21% oxygen (air). The total time at 1.3 ATA is 90 minutes. Each participant receives 40 pressure exposures (five days per week for eight weeks).

Total follow up for both treatment arms is 12 months.

Intervention Type
Other

Phase
Phase III

Primary outcome measure
Patient self assessment using the modified inflammatory bowel disease questionnaire (IBDQ), completed by the patient before treatment, 3, 6, 9 and 12 months post-treatment.

Secondary outcome measures
1. Physician assessment of bowel dysfunction using LENT SOMA scales of radiation injury, carried out before treatment, within two weeks of treatment finishing and at 12 months post-treatment
2. Patient self-assessments using European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire for Cancer patients (EORTC QLQ-C30) and defaecation problem subscale of the colorectal cancer-specific quality of life questionnaire module (QLQ-CR38), carried out before treatment, 3, 6, 9 and 12 months post-treatment
3. Photographic images of rectal mucosa taken via flexible sigmoidoscopy, taken before treatment, within 2 weeks of treatment finishing and at 12 months post-treatment

Overall study start date
01/11/2008

Completion date
01/12/2013

Eligibility

Key inclusion criteria
As of 09/10/2008, point five of the below inclusion criteria has been amended to:
5. Gastrointestinal symptoms attributable to prior radiotherapy (late effects in normal tissues subjective, objective, management and analytic scales [LENT SOMA] grade 1 with difficult intermittent symptoms, grades 2 - 3, plus patients with grade 4 rectal bleeding

At this time, the following criteria was also added:
8. Symptoms are not relieved by appropriate life-style advice and medication over a 3-month period

Initial information at time of registration:
1. Age over 18 years, either sex
2. Past history of a malignant pelvic neoplasm (T1-3 N0-1 M0)
3. Minimum 12 months follow-up post-radiotherapy
4. No evidence of cancer recurrence
5. Grade 1 - 3 gastrointestinal morbidity (late effects in normal tissues subjective, objective, management and analytic scales [LENT SOMA]) not present before radiotherapy
6. Physical and psychological fitness for hyperbaric therapy
7. Written informed consent and available for follow-up

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
75

Total final enrolment
84

Key exclusion criteria
As of 09/10/2008, the following points were added to the exclusion criteria:
11. Surgery for rectal cancer
12. Prior treatment with even a single dose of bleomycin

Initial information at time of registration:
1. Prior hyperbaric oxygen therapy
2. Claustrophobia
3. Epilepsy
4. Chronic obstructive airways disease
5. Bullous lung disease
6. Acute or chronic pulmonary infection
7. Uncontrolled asthma
8. Untreated pneumothorax
9. Previous middle/inner ear operations (except grommets and similar procedures) and/or irremediable inability to equalise middle ear pressure
10. Contra-indication or other inability to undergo magnetic resonance imaging, if required to rule out malignancy

Date of first enrolment
27/06/2011

Date of final enrolment
15/10/2012

Locations

Countries of recruitment
England

United Kingdom

Wales

Study participating centre
The Royal Marsden Hospital
London
United Kingdom
SW3 6JJ

Study participating centre
Hyperbaric Medicine Unit
St Richards Hospital
Chichester
United Kingdom
PO19 6SE

Study participating centre
London Hyperbaric
Whipps Cross University Hospital
London
United Kingdom
E11 1NR

Study participating centre
DDRC Healthcare
Plymouth
United Kingdom
PL6 8BU

Study participating centre
North of England Hyperbaric Services, Spire
East Riding Hospital
Kingston-upon-Hull
United Kingdom
HU10 7AZ

Study participating centre
DDRC Healthcare
South Wales Hyperbaric Medical Centre
Spire Cardiff Hospital
Cardiff
United Kingdom
CF23 8XL

Study participating centre
London Diving Chamber
Hospital of St John and St Elizabeth
London
United Kingdom
NW9 9NH

Study participating centre
The Diver Clinic
Poole
United Kingdom
BH15 2NN

Study participating centre
East of England Hyperbaric Unit
James Paget University Hospitals NHS Found Trust
Great Yarmouth
United Kingdom
NR31 6LA

Study participating centre
North West Emergency Recompression Unit
Murrayfield Hospital
Wirral
United Kingdom
CH61 1AU

Sponsor information

Organisation
Institute of Cancer Research (UK)

Sponsor details
Downs Road
Sutton, Surrey
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SM2 5PT

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) (ref: C181/A9694)

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

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	01/02/2016		Yes	No
Plain English results			26/10/2022	No	Yes