The effect of Hyperbaric OxygeN therapy on brEast cancer patients with late radiation toxicitY

Published: 28-08-2019
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To assess whether HBOT reduces pain, and improves physical functioning and QoL in breast cancer patients with late radiation toxicity.

Ethical review	Approved WMO
Status	Completed
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Interventional

Summary

ID

NL-OMON55553

Source
ToetsingOnline

Brief title
UMBRELLA HONEY

Condition

- Breast neoplasms malignant and unspecified (incl nipple)
- Breast disorders
- Breast therapeutic procedures

Synonym
Breast cancer, malignant breast tumor

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Vrienden UMC

Intervention

Keyword: Breast cancer, Hyperbaric oxygen therapy, Toxicity

Outcome measures

Primary outcome

Patient reported breast/chest wall pain.

Secondary outcome

Secondary endpoints are: physical functioning, QoL cosmetic outcome, physician reported pain and radiation toxicity (according to CTCAE criteria version 4.03), tissue oxygenation previous to HBOT and after HBOT and side-effects of HBOT.

Study description

Background summary

With both an increase in breast cancer incidence and an increase in breast cancer survival, the number of breast cancer survivors living with treatment-induced morbidity have increased. Over the past years, there has been a shift towards less invasive treatment of breast cancer. Radiotherapy plays an important role in the treatment of most breast cancer patients. Most breast cancer patients are nowadays treated with breast conserving therapy, a combination of lumpectomy and radiotherapy. However, radiotherapy on the chest wall may also be indicated after mastectomy when tumour was irradical resected, or with a remaining macroscopic tumour on the chest wall after resection. Also, radiotherapy in the axilla can be used to replace axillary lymph node dissection. Radiotherapy is crucial in reducing the risk of local recurrence and improving disease free survival. However, it may also lead to (late) radiation toxicity. Radiation toxicity is characterized by fibrosis, edema, pain, impaired mobility of the arm and decreased cosmetic outcome. (Late) radiation toxicity can decrease the quality of life (QoL) after breast cancer treatment. Treatment with hyperbaric oxygen therapy (HBOT) is being used to treat late radiation toxicity after i.e. head- and neck cancer, gynaecologic malignancies, urologic malignancies and breast cancer. HBOT induces neovascularisation and stimulation of collagen formation by fibroblasts. Even though HBOT is currently used in the treatment of late radiation toxicity in

the breast, and reimbursed by insurers, the evidence is scarce. Only a small number of (mostly single-arm) studies have been performed and shown improvement of complaints.

Study objective

To assess whether HBOT reduces pain, and improves physical functioning and QoL in breast cancer patients with late radiation toxicity.

Study design

Randomized controlled trial, nested within a prospective cohort (UMBRELLA, METC no. 15-165) according to the cmRCT design. UMBRELLA is a prospective cohort study including all breast cancer patients visiting the University Medical Center (UMC) Utrecht department of Radiotherapy. In total 240 patients will be randomized in a ratio of 2:1.

Intervention

Eligible patients will be referred to the HBO center for a standard HBO treatment. HBOT consists of 30-40 treatment sessions (1 session per day during 5 days per week). During the hyperbaric oxygen (HBO) sessions patients breath in 100% oxygen during 4 times 20 minutes in a hyperbaric chamber.

Study burden and risks

: Eligible patients will be referred to the HBO center as part of standard care. These patients will be offered to undergo a standard HBO treatment. HBOT consists of a total of 30-40 2 hours sessions in a hyperbaric chamber. In this hyperbaric chamber, which allows for a maximum of 12 people, patients wear oxygen masks for 4 times 20 minutes. During these sessions people may read or watch a movie. We expect that HBOT is beneficial for patients with late radiation toxicity. A reduction of pain and fibrosis and improvement of arm mobility and QoL might be expected. Possible side-effect of HBOT are (transient) myopia, fatigue, barotrauma (i.e. problems with clearing the ears due to the high pressure).
To assess the degree of late radiation toxicity (fibrosis, edema, (impaired) arm mobility and cosmetic outcome) in the HBOT group, an extra physical exam is performed at baseline and 3 months after HBOT. To evaluate cosmetic outcome, a medical photograph will be taken at both occasions. Skin oxygenation with transcutaneous oxygen measurement (TCOM) is measured as well. This is a non-invasive measurement. However, it might be a burden since patients will be undressed during this examination. At the end of the study, patients in the HBO group fill out the late radiation toxicity questionnaire.
Yet, HBOT is approved and reimbursed care, despite long term results are still

unclear.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Self reported pain grade 3-4 (on a scale of 1-4) as assessed by the late radiation toxicity questionnaire;
- Participation >12 months in the UMBRELLA cohort;
- Previous treatment with radiotherapy for breast cancer;
- Finished surgery and (neo)adjuvant systemic therapy except adjuvant endocrine therapy, for breast cancer.

Exclusion criteria

- Poor responder (i.e. return of <= 2 UMBRELLA questionnaires);
- Previous HBOT;
- Contra-indications for HBOT (e.g. (severe) COPD/asthma, pacemaker, morbid obesity, epilepsy in medical history, severe heart failure);
- Current metastatic disease or recurrent breast cancer.

Additional exclusions criteria based on screening visit:
- Inability to follow schedule of all consecutive HBO treatments (e.g. due to scheduled holidays > 2 days);
- Not meeting criteria for HBOT (e.g. due to complaints similar to late radiation toxicity, not caused by radiotherapy).

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	04-12-2019
Enrollment:	240
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Conoxia Liquid / Medicinal Oxygen Liquid SOL

Generic name:	Oxygen
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	28-08-2019
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	14-10-2019
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	12-02-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	25-02-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	21-10-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	29-10-2021
Application type:	Amendment
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2019-002635-28-NL
CCMO	NL69081.041.19

Study results

Date completed: 08-05-2023

Results posted: 07-03-2024

First publication
08-02-2024