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Deep-inspirational breath hold during breast radiotherapy

Submission date
09/02/2021

Recruitment status
No longer recruiting

Registration date
12/02/2021

Overall study status
Completed

Last Edited
30/03/2023

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Radiotherapy plays an essential role in the management of breast cancer. After undergoing breast-conserving surgery most patients need postoperative whole-breast or partial breast irradiation. Most breast cancer patients become long-term survivors, so treatments should not endanger the patients' general health and well-being. The main radiation-related hazards are radiogenic heart and lung damage resulting in significant illness many years or decades after the radiotherapy. The risk of radiogenic heart damage is dose-dependent, but no lower threshold with the absence of risk has been identified. Hence all efforts should be made to avoid or lessen heart radiation exposure as much as possible. There are many approaches to protect the heart from radiation exposure. The breath-holding technique first used in breast cancer in 2001 only recently became widespread. Its greatest impact is a reduced radiation dose to the heart and to a lesser extent to the lung. Nevertheless, the benefit varies according to the patient's anatomy and lung capacity, and on occasion the absence of advantage or even elevated heart doses have been described. The aim of this study is to assess the usefulness of the Deep-Inspirational Breath-Hold (DIBH) technique in left breast cancer radiotherapy.

Who could participate?
Patients aged over 18 with left-sided breast cancer who need postoperative radiotherapy

What does the study involve?
Usual radiotherapy is delivered for all patients, with the DIBH technique used if it is feasible. All the patients go through planning CT examinations in the supine position (lying on their back) while both free-breathing and DIBH, and those who need whole breast radiotherapy receive CT also in the prone position (lying on their front).

What were the possible risks and benefits?
The only risk is the extra radiation dose from the extra CT scans. The possible benefits are reduced radiation dose to the risk organs if the DIBH technique is used (most patients), and the detailed and careful dose analyses carried out. Extra attention is paid to all participants as is usual in all clinical studies.

Where is the study run from and how long is it expected to run for?
July 2017 to December 2019

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
#272/2017

Study information

Scientific Title
Deep-Inspirational Breath-Hold (DIBH) technique in Left-sided Breast Cancer: individual decision-making is needed on its use

Acronym
DIBH-LBC

Study objectives
The DIBH technique is appropriate to reduce heart doses in most cases, however, not all patients are appropriate for the technique, and not all benefit from it even if appropriate.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/02/2018, Institutional Ethics Review Board of the University of Szeged (Regional Human Biomedical Research Ethics Committee, 6720 Szeged, Dugonics tér 13, Hungary; +36 (0) 62 545997; office.rkeb@med.u-szeged.hu), ref: 272/2017

Study design
Prospective interventional single-arm cohort study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Left breast cancer needing adjuvant radiotherapy

Interventions
Conventional radiotherapy is used with the DIBH technique, and doses to the normal tissues, risk organs are analyzed in comparison to that if DIBH is not practised (free-breathing supine or if the patient is positioned prone). The radiotherapy is given in 25 fractions, five fractions per week. Dosimetry data are analyzed in radiotherapy plans generated under DIBH, free-breathing in the supine position, and in the prone position for individual patients. All three techniques are widely used in practice.

Intervention Type
Other

Primary outcome(s)
Heart and LAD doses measured using dosimetry data extracted from radiotherapy plans at the time of treatment planning, before the start of the individuals' radiotherapy, and analyzed both individually before the radiotherapy and later on as a database after the last patient's

radiotherapy. Dosimetry data analyzed individually whether the target dose constraints were achieved or not, and as a database using statistical methods (repeated ANOVA test and paired t-test).

Key secondary outcome(s))
Lung, breast/chest wall and lymph node doses measured using dosimetry data extracted from radiotherapy plans at the time of treatment planning, before the start of the individuals' radiotherapy, and analyzed both individually before the radiotherapy and later on as a database after the last patient's radiotherapy. Dosimetry data were analyzed individually whether the target dose constraints were achieved or not, and as a database using statistical methods (repeated ANOVA test and paired t-test).

Completion date
31/12/2019

Eligibility

Key inclusion criteria
1. Patients >18 years old who have left-sided breast cancer
2. Eligible for postoperative radiotherapy
3. No comorbidity that could prevent practising DIBH (bronchial asthma, obesity, hypacusis etc)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
130

Key exclusion criteria
Presence of COPD, bronchial asthma or another severe comorbidity that would hinder cooperation during DIBH (extreme obesity, mental disorder, hypacusis)

Date of first enrolment
23/01/2018

Date of final enrolment
13/11/2019

Locations

Countries of recruitment
Hungary

Study participating centre
University of Szeged
12 Korányi fasor
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Sponsor information

Organisation
University of Szeged

ROR
https://ror.org/01pnej532

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Zsuzsanna Kahán (kahan.zsuzsanna@med.u-szeged.hu) and Zoltán Varga (varga.zoltan@med.u-szeged.hu). The information may be provided upon request from now up to 2 years to professional teams or societies. Various dosimetry data have been collected and analyzed by statistical methods according to patient- and radiotherapy-related aspects. The patients agreed to use or share their data after anonymisation without restrictions or comments.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		13/05/2021	13/08/2021	Yes	No
Other files	Supplementary information, questionnaire regarding the comfort of the RT procedure	13/05/2021	30/03/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file			01/03/2021	No	No
Protocol file			01/03/2021	No	No