Exploratory study on nasal high flow therapy for breath hold in radiotherapy (ENTheR-study)

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The objective of this study is to investigate the feasibility of treating breast and lung cancerpatients in mDIBH using nasal a high-flow therapy (NHFT) device.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON46151

Source
ToetsingOnline

Brief title
ENTheR-trial

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
lung and breast cancer

Research involving
Human

Sponsors and support

Primary sponsor: MAASTRO clinic
Source(s) of monetary or material Support: MAASTRO clinic

Intervention

Keyword: Breath hold, Exploratory, Nasal, Radiotherapy

Outcome measures

Primary outcome

Tolerability of the treatment, defined as the proportion of patients completing

the

treatment (CT-scan and all treatment sessions) in breath hold conditions using

NHFT

Secondary outcome

Proportion of patients able to do at least one breath hold of 90 seconds with

NHFT

during the training session.

* Stability of the BH within one BH.

* Reproducibility of BH within one session and between different sessions.

* Subjective tolerance.

* Dose difference (mean lung dose, mean heart dose, lung V5 and esophageal dose)

between standard treatment plan and treatment plan in breath hold with NHFT.

Study description

Background summary

Due to breathing and other motion, tumors, such as breast and lung cancer, as well as their
surrounding organs (e.g. the heart), move, which poses a challenge for radiotherapy treatment.
Reducing or even stopping breathing, e.g. by irradiating during inspiration, is a way to decrease

tumor and organ motion resulting in a reliable target coverage with smaller margins. These
smaller margins can result in a better sparing of normal tissues. Furthermore, in some patients,
during inspiration the heart may move away from the target volume making it possible to better
spare the heart. Finally, during inspiration, the lung volume is larger and the lung density is
lower, which can lead to a lower dose to the surrounding normal lung tissue. Reduction of
radiation dose to normal tissues leads to less radiation-induced toxicity. This makes treating
breast and lung cancer patients in breath hold (BH) conditions an attractive strategy. A BH has
to be stable and long enough for the duration of a planning CT-scan, cone beam CT (CBCT)
scan and treatment delivery. Treatment of left-sided breast cancer with radiotherapy in
moderate deep inspiration breath hold (mDIBH) is well established. Also, in MAASTRO clinic,
left-sided breast cancer patients are treated in mDIBH, but this is done without any support or
control of the breath hold. Standard BH durations in RT treatment are around 20 seconds,
which is not enough to perform a complete CBCT. The health status of lung cancer patients is
generally worse compared with breast cancer patients, making it more difficult to treat this
patient group during breath hold. mDIBH in lung cancer patients is therefore not widely used,
and not yet performed in MAASTRO clinic. Ventilation techniques that can support patients in
holding their breath might make it a feasible approach in patients with a less favourable
performance status, and might increase the duration of a breath hold. Nasal High Flow Therapy
(NHFT) is a non-invasive system that provides controlled oxygen concentrations and low levels
of positive pressure via a nasal interface. NHFT improves oxygenation in diverse patient
groups, and is increasingly used as an alternative to mechanical ventilatory support. It has
been shown to be a safe device in several clinical situations and patient populations, such as
in COPD patients, but also in apneic conditions under general anesthesia. It has however
never been used in the context of breath hold support, neither has it been used

in radiotherapy
practice. We hypothesize that supporting BH with nasal high flow therapy (NHFT) will allow
robust radiotherapy treatments of moving targets in a broad patient population allowing for BHs
that are long enough, stable and reproducible during a whole treatment course.

Study objective

The objective of this study is to investigate the feasibility of treating
breast and lung cancer
patients in mDIBH using nasal a high-flow therapy (NHFT) device.

Study design

Exploratory study

Study burden and risks

For the patient, the burden consists of an extra CT-scan and some extra time for the instruction of the Nasal High Flow Therapy. The extra radiation is minimal (12mSv) and the time spent by the patient for the use of the therapy is predicted to benefit them during radiation.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Locally advanced lung cancer or oligometastatic patients with *local* stage III, treated with curative or radical intent OR
- Left-sided breast cancer patients treated with radiotherapy with curative intent.
- WHO* 2
- * 18 years old
- Able to give informed consent
- Willing to be treated in Maastricht (treatment not possible in Venlo)

Exclusion criteria

- Patient refusal
- Hypercapnic COPD patient

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped

Start date (anticipated):	30-04-2019
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	22-01-2019
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	25-02-2019
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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
ClinicalTrials.gov	NCT03729661
CCMO	NL68019.096.18