Long term effects of definitive chemoradiotherapy on respiratory function tests in patients with locally advanced (non) small cell lung carcinoma

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Ethical review	Not approved
Status	Will not start
Health condition type	Respiratory tract neoplasms
Study type	Observational non invasive

Summary

ID

NL-OMON42847

Source
ToetsingOnline

Brief title
Long term effects of chemoradiotherapy on respiratory function in (N)SCLC

Condition

- Respiratory tract neoplasms

Synonym
(N)SCLC, lungcancer

Research involving
Human

Sponsors and support

Primary sponsor: Haga ziekenhuis

Source(s) of monetary or material Support: Geld van eigen afdeling

Intervention

Keyword: (N)SCLC, Chemoradiotherapy, Pulmonary function

Outcome measures

Primary outcome

The change of lung function at least one year after chemoradiotherapy (long

term changes) in our clinic.

Secondary outcome

not applicable

Study description

Background summary

Radiation induced lung injury is common in patients receiving thoracic radiotherapy. Radiotherapy-induced pulmonary symptoms (shortness of breath and cough) occur in approximately 5-20% of patients irradiated for breast cancer, lymphoma or lung cancer. 50-90% of these patients have declines in pulmonary function tests (PFTs) (8)

Radiation induced lung injury can be divided in early injury (3- 6 months after treatment), most of the time radiation pneumonitis and late injury (from 1 year after treatment, chronic fibrosis). Previous studies show the first decline in PFT in 6 months and further decline beyond 1 year (3, 4). During treatment with (chemo) radiation there is no change in PFT (1,2,6).

The change in pulmonary function is dependent on the mean lung dose (2,3, 5) and pre-existing lung disease (3,9). Concurrent chemotherapy has an additional negative effect on pulmonary function (5, 7,10) From previous studies in breast cancer en lymphoma it is known that the changes in PFT values can be estimated before treatment (6).

Study objective

The aim of the study is to evaluate the change of lung function at least one year after definitive chemoradiation (concurrent or sequential) in patients

with locally advanced (non) small cell lung carcinoma to assess late radiation injury in our patient population (patients treated in a large non academic teaching hospital). Our aim is to see if our results match the results found in literature.

Study design

Patients who received either sequential or concurrent treatment with chemoradiation in the period between November 2010 and November 2015 will be selected restrospective from the electronical patient file (Hix) in the Haga hospital. All patients who were treated had pulmonary lung function testing done before start of the treatment, including both spirometry, with measurement of forced capacity (VC) and forced expiratory volume in 1 second (FEV1), and measurement of diffusion capacity to carbon monoxide (DLCO).
The patients who meet our in-and exclusion criteria will be asked to have another pulmonary function test done in our pulmonary function testing laboratory >1 year after finishing their treatment in order to study the change in lung function due to long term radiation induced lung injury (fibrosis).

The results will be correlated with smoking history and smoking after treatment as well. The mean lung dose will also be used by evaluating the decline of lung function. We will also look at histology and effect of either sequential or concurrent treatment.

Study burden and risks

Burden: one extra isit to the hospital. This will take about 60 minutes including medical history and pulmonary function testing.

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

1. * 18 years of age
2. Histologically of cytologically confirmed diagnosis of (N)SCLC
3. Stage II/III non operable disease
4. Treatment with definite concurrent of sequential chemoradiation between November 2010 and November 2015
5. Lung function testing including DLCO measurement pre-treatment is available
6. Signed written informed consent

Exclusion criteria

Not being able to have another lung function test done (due to death or poor condition)

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	45
Type:	Anticipated

Ethics review

Not approved

Date:	24-11-2016
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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
CCMO	NL59431.098.16