Long term effect 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 invasive

Summary

ID

NL-OMON53171

Source
ToetsingOnline

Brief title
Chemoradiotherapy and lung function changes in (N)SCLC

Condition

- Respiratory tract neoplasms

Synonym
(N)SCLC, lungcancer

Research involving
Human

Sponsors and support

Primary sponsor: HagaZiekenhuis

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

Intervention

Keyword: (N)SCLC, Chemoradiotherapy, Pulmonary function

Outcome measures

Primary outcome

Change in FEV1 and DLCO >1 year after treatment with radiotherapy or

combination treatment with chemoradiotherap either concurrent or sequential.

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)

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

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

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) or radiotherapy

alone 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

Retrospective selection of patients with prospective analysis of pulmonary function changes.The setting of this study is the pulmonary function laboratory, part of the Pulmonology Department, Haga Teaching Hospital, The Hague, The Netherlands. The study will start December 2016. At the latest it will end in March 2017

Study burden and risks

Burden: an extra visit to the oupatient clinic. This will take 60 minutes including medical history and pulmonary function testing wit finger prick.
Risks: none

Contacts

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Scientific
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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 invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	40
Type:	Anticipated

Ethics review

Not approved

Date:	27-03-2017
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	NL60077.098.16