Long-term Patient Related OuTcomEs in lung Cancer Treatment (PROTECT): Influence of patient decisions on QOL, functionality and survival.

Published: 16-07-2018
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Primary objective1) To assess and compare overall QOL during each subsequent line and type of therapy.Secondary objectives:2) To assess and compare therapy satisfaction / decision regret during each subsequent line and type of therapy.3) To assess...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Respiratory tract neoplasms
Study type	Observational non invasive

Summary

ID

NL-OMON46656

Source
ToetsingOnline

Brief title
Quality of life in lung cancer patients

Condition

- Respiratory tract neoplasms

Synonym
lung cancer

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Leeuwarden

Source(s) of monetary or material Support: Wetenschapsfonds Medisch Centrum Leeuwarden

Intervention

Keyword: Lung cancer, Quality of death, Quality of life, Shared decision making

Outcome measures

Primary outcome

Primary endpoint

1) QOL as assessed by questionnaires (QLQ-C30, QLQ-LC13) (sum scores and different subdomains).

Secondary outcome

Secondary endpoints

2) Treatment satisfaction / decision regret as assessed by questionnaires (CTSQ / DRS) (sum scores and different subdomains).

3) Treatment motives as assessed by questionnaire (OPT) (subdomain scores).

4) QOL (QLQ-C30, QLQ-LC13), treatment satisfaction / decision regret (CTSQ / DRS) and treatment motives (OPT).

Other study parameters

4D. For endpoints 1), 2) and 3), patient and disease characteristics (see parameters under 5.2) will be assessed as potential predictors.

4E. For secondary endpoint 2), treatment motives (OPT-score), decision control (CPS), symptom burden (QLQ-LC13), treatment tolerance / efficacy and QOL (QLQ-C30) will be assess as additional potential predictors.

4F. For secondary endpoint 3), symptom burden (QLQ-LC13), treatment tolerance /

efficacy and quality of life (QLQ-C30, QODDQ/EuroQ2) will be assess as

additional potential predictors.

Study description

Background summary

Annually more than 12.000 patients are diagnosed with lung cancer in the Netherlands and those numbers are increasing. Non-small cell lung cancer (NSCLC) is accounting for 75% of all cases. At time of diagnosis, approximately 50% of all patients already have advanced disease and can only be treated with systemic therapies (chemotherapy, targeted therapy, immunotherapy or radiotherapy alone) or best supportive care. Since these therapies result in only small improvements in survival rates and may frequently lead to adverse events with a negative impact on quality of life (QOL) a good risk-benefit weighing is of great importance to help an individual patient in decision making. Yet, de clues to make the right decisions are far from clear. For proper decision making and preventing regret of choices patients and doctors need more information.
In the recent years, insights in optimizing cancer care are changing and QOL is emerging as an important outcome. This is meaningful because for patients, the impact of treatment on active life expectancy may be as important as extension of life itself.
The main objective of this study is to gain insight in the quality of life of a real-life population of stage III-IV NSCLC patients treated with systemic therapy (in case of stage III in intention curative) or supportive care, in the period from diagnosis (baseline) till death or discontinuation of follow up.

Study objective

Primary objective
1) To assess and compare overall QOL during each subsequent line and type of therapy.

Secondary objectives:
2) To assess and compare therapy satisfaction / decision regret during each subsequent line and type of therapy.
3) To assess and compare treatment motives at start and during of each subsequent line and type of therapy.
4) To identify predictors of overall QOL, therapy satisfaction / decision regret and treatment motives during each subsequent line and type of therapy.*

Study design

This study is a prospective single centre cohort study.

Study burden and risks

The burden associated with this study includes repeatedly filling in questionnaires. At baseline, patients characteristics will be documented and several questionnaires will be completed. Subsequently, every six weeks a series of additional questionnaires will be distributed. This six weeks frequency will be synchronized with normal clinical follow up, which is scheduled every 3 weeks for patients receiving chemotherapy or 2 weeks for patients receiving immunotherapy. Follow-up is designed such that the majority can be done online via MijnMCL or collected via EPIC and will not interfere with regular care. The after-death questionnaire will then be send to a relative (registered at baseline) three weeks after decease.
The risk and discomfort of these study is neglectable. Filling in the repeated questionnaires will cost some time (approximately one hour per six weeks).
The results of this study may be important for future lung cancer patients, as it may help to understand the relationship between cancer treatment and quality of life and quality of death, so that future patients can helped making important treatment decisions.

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

Newly diagnosed stage III or IV lung cancer, both histopathological proven as clinical diagnosis in patients not able to undergo invasive diagnostics.
Patients must be able to understand and complete protocol requirements, Instructions, and questionnaires provided in Dutch

Exclusion criteria

First line of cancer treatment for stage III or IV started in another hospital

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	27-11-2018
Enrollment:	500
Type:	Actual

Ethics review

Approved WMO Date:	16-07-2018
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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	NL63466.099.17