Quality of life in advance stage lung cancer

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22982

Source
NTR

Brief title
Lung cancer, quality of life, quality of death, shared dicision making

Health condition

Lung cancer and quality of life

Longkanker en kwaliteit van leven

Sponsors and support

Primary sponsor: Medical Center Leeuwarden
Henri Dunantweg 2
8934 AD Leeuwarden
Source(s) of monetary or material Support: Medical Center Leeuwarden
Henri Dunantweg 2
8934 AD Leeuwarden

Intervention

Outcome measures

Primary outcome

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) (rankings and subdomain scores).

4) QOL (QLQ-C30, QLQ-LC13, QODDQ/EuroQ2), treatment satisfaction / decision regret (CTSQ / DRS) and treatment motives (OPT).

Other study parameters

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

4B. 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.

4C. 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

The main objective of this study is to assess and compare the overall QOL of a real-life population of stage III-IV NSCLC patients during each subsequent line and type of therapy, thereby covering the total period from diagnosis (baseline) till death or discontinuation of follow up. Secondly, we aim to asses and compare treatment satisfaction, decision regret and treatment motives during each line and type of therapy. Finally, we aim to identify predictors of QOL, treatment satisfaction, decision regret and treatment motives during each line and type of therapy.

Patients will be recruited from the pulmonary or oncologic outpatient clinic of the Medical

Centre Leeuwarden. Patients are newly diagnosed with stage III or IV lung cancer, both histopathological proven as clinical diagnosis in patients not able to undergo invasive diagnostics.

Our only exclusion criteria is patients received first line of cancer treatment for stage III or IV in another hospital.

At baseline, patient 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.

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 be helped making important treatment decisions.

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

Next at baseline, patient characteristics will be documented (mainly using data already collected for the Dutch Lung Cancer Audit (DLCA)), and three questionnaires will be completed. Subsequently, every six weeks a series of four questionnaires will be distributed. This interval corresponds to the regular follow up periods and evaluation of therapy.

We consider quality of death to be the last measurement of QOL, therefor an after-death questionnaire will then be send to a relative three weeks after decease.

Intervention

NONE (observational study of regular care)

Contacts

Public
Medical Centre Leeuwarden, Department of Respiratory Medicine

R.G.P. Gijtenbeek
Henri Dunantweg 2

Leeuwarden 8934 AD
The Netherlands
+31582867752
Scientific
Medical Centre Leeuwarden, Department of Respiratory Medicine

R.G.P. Gijtenbeek
Henri Dunantweg 2

Leeuwarden 8934 AD
The Netherlands
+31582867752

Eligibility criteria

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
Intervention model:	Other

Control: N/A , unknown

Recruitment

NL

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

Ethics review

Positive opinion

Date:	04-06-2018
Application type:	First submission

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
NTR-new	NL7053
NTR-old	NTR7258
Other	/ Medisch Centrum Leeuwarden: RTPO 1020 : ABR: NL63466.099.173

Study results

Summary results
None