Quality of life in advance stage lung cancer

Gepubliceerd: 04-06-2018 Laatst bijgewerkt: 18-08-2022

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)...

Ethische beoordeling Positief advies **Status** Werving gestart

Type aandoening -

Onderzoekstype Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22982

Bron

Nationaal Trial Register

Verkorte titel

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

Aandoening

Lung cancer and quality of life

Longkanker en kwaliteit van leven

Ondersteuning

Primaire sponsor: Medical Center Leeuwarden

Henri Dunantweg 2 8934 AD Leeuwarden

Overige ondersteuning: Medical Center Leeuwarden

Henri Dunantweg 2 8934 AD Leeuwarden

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

NONE (observational study of regular care)

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type: Observationeel onderzoek, zonder invasieve metingen

Onderzoeksmodel: Anders

Controle: N.v.t. / onbekend

Deelname

Nederland

Status: Werving gestart

(Verwachte) startdatum: 27-11-2018

Aantal proefpersonen: 500

Type: Verwachte startdatum

Ethische beoordeling

Positief advies

Datum: 04-06-2018

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register ID

NTR-new NL7053 NTR-old NTR7258

Ander register / Medisch Centrum Leeuwarden: RTPO 1020 : ABR: NL63466.099.173

Resultaten

Samenvatting resultaten

None