Patiënt gerapporteerde symptoom monitoring door middel van een web applicatie bij longkankerpatiënten

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29336

Source NTR

Brief title SYMPRO-Lung

Lung cancer

Health condition

Sponsors and support

Primary sponsor: Amsterdam UMC, location VUmc, Antoni van Leeuwenhoek hospital, Integraal Kankercentrum Nederland (IKNL) **Source(s) of monetary or material Support:** Roche, Zorg Innovatiefonds, Stichting Kwaliteitsgelden Medisch Specialisten (SKMS)

Intervention

Outcome measures

Primary outcome

The primary end-point of this study is the difference in QoL between baseline and 15 weeks,

6 months, and 12 months post start of treatment (EORTC QLQ C30) between the intervention groups (PRO symptom monitoring) and standard care group. An effect size (ES) of 0.4 is considered a clinically relevant difference between the PRO symptom monitoring intervention and standard care. An ES of less than 0.2 between the active and a reactive approach is considered as a non-inferior difference.

Secondary outcome

Secondary outcome measures include:

- 1-year PFS
- 1-year OS
- 1-year recurrence rate

• Symptom incidence and severity over time (PRO-CTCAE for the intervention group only and EORTC QLQ lung module (LC-13) for both groups)

• Medication adherence (OACA) (Medication Adherence Report Scale (MARS-5)) and Believes about Medicine Questionnaire (BMQ)

• Cost-effectiveness (Euroqol-5 Dimensions with 5 levels (EQ-5D-5L) and clinical healthcare costs data)

• Implementation fidelity (intervention group only; quantitative and qualitative patient and HCP reported).

Study description

Background summary

Lung cancer treatment related side effects and the manifestations of this disease cause a wide range of symptoms (e.g. dyspnea, cough, and pain) that can impact the patients' quality of life (QoL) and medication adherence. Recent trials show that the use of patient reported outcomes (PROs) to monitor symptoms during and after cancer treatment does not only improve symptom management, but also significantly improves QoL and overall survival (OS). These results highlight the importance of implementation of PRO symptom monitoring tools. However, the methods used in these studies are based on a demanding follow-up system and has yet to take a more clinical practice approach, by making the system more patient-centered. In the SYMPRO-Lung study we will assess whether a more patient-centered approach (reactive intervention) will achieve similar results compared to the more labor intensive active follow up approach (active intervention).

The primary objective is to compare the effect of a weekly PRO symptom monitoring (mobile) website during and after treatment on the QoL of lung cancer patients with standard care. In addition non-inferiority between the active and reactive approach will be tested. Secondary objectives include assessing the effect of PRO-symptom monitoring on progression-free survival (PFS), OS, the incidence and grade of PRO symptoms, medication adherence, implementation fidelity and cost-effectiveness.

This study follows a stepped wedge design which entails that every participating hospital starts with a period in which patients are included as controls. At different time points the hospitals randomly switch towards using the intervention. Collaborating hospitals are grouped together in a cluster. The hospitals will be randomized between an active and reactive intervention.

Patients weekly fill out a PRO list of symptoms. The (mobile) website generates an alert when the severity of PRO-symptoms exceed a predefined threshold. In the active approach the health care providers (HCPs) are instructed to call the patients within 24 hours, in the reactive approach the patients are instructed to contact their HCP to discuss their symptoms. When in doubt, patients are instructed to always call the hospital in both approaches.

Study objective

We aim to compare the effect of PRO-symptom monitoring with PRO-CTCAE based questions on Quality of Life (QoL) using a (mobile) website in lung cancer patients treated within a clinical care setting. Our hypothesis is that patients using the PRO-symptom monitoring through the (mobile) website have an improved QoL compared to patients in usual care.

Study design

- T0 Baseline
- T1 15 weeks
- T2 6 months
- T3 12 months

Intervention

Patients fill out a list of PRO symptoms weekly using a (mobile) website. The (mobile) website generates an alert when the severity of PRO-symptoms exceed a predefined threshold. In the active approach the HCPs receive an email with the symptoms that exceed the predefined threshold. They are instructed to contact the patient, on working days within 24 hours, to discuss the results. Outside of working hours patients are instructed to contact their HCP. In the reactive approach patients are instructed by a push notification or e-mail to contact their HCP.

Contacts

Public

Amsterdam UMC, location VUmc Annemarie Becker-Commissaris

020 444 1215 Scientific

Amsterdam UMC, location VUmc Annemarie Becker-Commissaris

020 444 1215

Eligibility criteria

Inclusion criteria

- Cytological or histologically proven or radiological suspect small or non-small cell lung cancer patients.

- Patients that are starting (new) treatment with radiotherapy, surgery, chemotherapy, immunotherapy or targeted therapy, or a combination.

- Age 18 years or older.

- ECOG Performance Status classification should be 0, 1 or 2.
- Access to internet.

Exclusion criteria

- Participating in a treatment study, when a structured symptom reporting is already part of such a study.

- Life expectancy at moment of inclusion is shorter than 15 weeks.

- The patient's treatment and follow up does not remain in an affiliated hospital.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	13-10-2019
Enrollment:	584
Туре:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description

After an embargo period of four years, the crude and processed data can be accessed under specific conditions and after request to Amsterdam UMC, AVL/NKI and IKNL. When researchers would like to reuse the data, written consent should be asked to the PIs of this study. Use of the data by third parties will then be reviewed for each research question. Next to that, the project group will depict at least three co-authors from the original project group to be included on articles resulting from third parties analyses.

Ethics review

Positive opinion	
Date:	24-07-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 50136 Bron: ToetsingOnline Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7897
ССМО	NL68440.029.18

Register
OMON

ID NL-OMON50136

Study results