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

Gepubliceerd: 24-07-2019 Laatst bijgewerkt: 19-03-2025

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29336

Bron
Nationaal Trial Register

Verkorte titel
SYMPRO-Lung

Aandoening

Lung cancer

Ondersteuning

Primaire sponsor: Amsterdam UMC, location VUmc, Antoni van Leeuwenhoek hospital, Integraal Kankercentrum Nederland (IKNL)
Overige ondersteuning: Roche, Zorg Innovatiefonds, Stichting Kwaliteitsgelden Medisch Specialisten (SKMS)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Amsterdam UMC, location VUmc
Annemarie Becker-Commissaris

020 444 1215

Wetenschappelijk

Amsterdam UMC, location VUmc
Annemarie Becker-Commissaris

020 444 1215

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	13-10-2019
Aantal proefpersonen:	584

Type: Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Toelichting
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.

Ethische beoordeling

Positief advies
Datum: 24-07-2019
Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50136
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7897
CCMO	NL68440.029.18
OMON	NL-OMON50136

Resultaten