Titel Symptom monitoring with patient-reported outcomes using a web application among lung cancer patients in the Netherlands (SYMPRO-LUNG)

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Interventional

Summary

ID

NL-OMON50136

Source
ToetsingOnline

Brief title
SYMPRO-Lung

Condition

- Miscellaneous and site unspecified neoplasms benign
- Respiratory tract neoplasms

Synonym
Lung cancer, Lung carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Roche,SKMS (stichting Kwaliteitsgelden Medisch Specialisten) en innovatiefonds

Intervention

Keyword: Lung cancer, Medication adherence, Patient Reported Outcomes (PRO□s), Symptom monitoring

Outcome measures

Primary outcome

The primary outcome is to measure the difference in QoL (EORTC QLQ C30 score),

15 weeks after the start of the treatment.

Secondary outcome

Secondary aims are studying the effect of PRO symptom monitoring, active versus

reactive, and intervention compared to standard care through the following

outcomes

- Symptoms will be measured post treatment, at 15 weeks, 6 months and 12

months, by using the EORTC QLQ lung module (LC-13). The LC-13 measures specific

treatment related symptoms of lung cancer.

- Recurrence will be measured at 15 weeks, 6 and retrospectively at 12 months

post treatment by posing a single question to the HCPs querying occurrence

and/or time of recurrence. OS data will be retrieved from the Dutch Cancer

Registry (NKR) and will be defined as time from start of treatment until death.

- Medication adherence will be assessed using the Medication Adherence Report

Scale (MARS-5) at 15 weeks, 6, and 12 months.

- Cost effectiveness will be analyzed by determining the incremental cost

effectiveness and cost-utility ratio of each strategy. An externally validated model on cost-effectiveness using observational data will be used to compare the two PRO symptom monitoring approaches. Observational data will be obtained by a link with the NKR, Dutch Hospital Data (DHD) and Vectiz as well as the Euroqol-5 Dimensions with 5 levels questionnaire (EQ-5D).

- The implementation fidelity will be analysed using a mixed methods design with quantitative and qualitative data to investigate the implementation process of the PRO symptom monitoring app.

Study description

Background summary

Lung cancer and its treatment provide a wide range of symptoms and side effects in the patient such as dyspnea, cough and pain. These symptoms have a significant impact on the quality of life of patients. Recently, several trials have shown that the use of patient reported outcomes (PROs) for monitoring these complaints not only improves symptom management, but also significantly improves quality of life (QOL) and overall survival (OS). Potential underlying mechanisms for these results are the earlier response in case of severe symptoms, such as the more frequent prescription of supportive medication, dose adjustments or referrals.

Study objective

The primary aim of the study is to compare the effect of PRO symptom monitoring with standard care on QoL both during and up to 1 year after treatment.
Secondary aims are studying the effect of PRO symptom monitoring compared to standard care on the incidence and severity of PRO symptoms, medication adherence, progression, OS and cost effectiveness.
Additionally, we will compare an active follow up approach with a reactive approach of PRO symptom monitoring, study the influence of monitoring medication adherence of patients using oral anticancer agents (OACAs) compared to standard care and study the implementation fidelity of implementing the PRO symptom monitoring tool within the clinical practice setting.

Study design

The study uses a stepped wedge design. This means that every hospital starts with a control period in which only control patients are included. Over a period of 16 months, the hospitals will consecutively switch to the intervention. Participating hospitals are randomized between either active or reactive monitoring of symptoms.

Intervention

The intervention of this study consists of a web-based application that can be used via a mobile phone (or laptop/ computer/ tablet) to monitor symptoms and medication adherence. The symptoms of patients and will be queried through the app by using a subset of questions that are clinically relevant for lung cancer patients. For patients using OACAs the app also monitors medication adherence and gives advice
Adherence of the web-based application use is encouraged by weekly reminders through a push notification. A scoring algorithm will be used to assess the severity of the reported symptoms and medication adherence.
The active intervention group
The alert will be sent by (secured) e-mails to the health care practitioners (HCPs). HCPs are then expected to contact the patient (during office hours) within 24 hours on working days to give a tailored advice and to explore whether a visit to the hospital, or other interventions are required. Patients can, however, call or visit the hospital 24 hours a day and 7 days per week in case of an emergency.
The reactive intervention group
With the reactive approach, the automatic alert provides patients with a push notification containing the advice to contact the hospital themselves within 24 hours. Patients can call or visit the hospital 24 hours a day and 7 days per week in case of an emergency. The PRO-data will be accessible during a HCPs consultation.
All patients will also receive the written standard of care patient information that is provided for the specific treatment they receive e.g. immediately contact the HCP in case of fever. In this information specific instructions are provided when to contact the treating HCPs (e.g. in case of fever).

Study burden and risks

The burden on patients consists of the extra time they have to spend on completing the weekly symptoms list, and the 4 measurement moments (baseline, 15 weeks, 6 and 12 months). Potential risks for the participating patients is classified as negligible.

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

Cytological or histologically proven or radiological suspect small or non-small cell lung cancer patients that are starting treatment with radiotherapy, surgery, chemotherapy, immunotherapy or targeted therapy, or a combination. Other inclusion criteria are 18 years and older, ECOG Performance Status classification should be 0,1 or 2 and access to internet.

Exclusion criteria

Patients who are participants of a treatment study or when their life expectancy at moment of inclusion is shorter than 15 weeks. The patient*s treatment and follow up will have to remain in an affiliated hospital

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-10-2019
Enrollment:	584
Type:	Actual

Medical products/devices used

Generic name:	SYMPRO-Lung
Registration:	No

Ethics review

Approved WMO Date:	12-07-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-09-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-10-2019
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-11-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-11-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-02-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-04-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-06-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-07-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-03-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 29336
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL68440.029.18
OMON	NL-OMON29336