

NUtritional Assessment in Non-small Cell lung cancer patients

Published: 14-06-2018

Last updated: 12-04-2024

The primary goal of this study is to gain insight changes in components of nutritional status and functional capacity over time. The objective is to improve the multidisciplinary health care for lung cancer patients. Secondary goals are to investigate...

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| Ethical review | Approved WMO |
| Status | Recruitment stopped |
| Health condition type | Respiratory and mediastinal neoplasms malignant and unspecified |
| Study type | Observational non invasive |

Summary

ID

NL-OMON50451

Source

ToetsingOnline

Brief title

NUANCE study

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified

Synonym

lungcancer, Non Small Cell Lung Cancer

Research involving

Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis

Source(s) of monetary or material Support: Nutricia, Nutricia Medical Nederland B.V.

Intervention

Keyword: lung cancer, nutritional assessment, Oncology, physical functioning

Outcome measures

Primary outcome

Nutritional status measured with the PG-SGA, bio-impedance, CT and self reported physical functioning, physical activity and functional status (SPPB score).

Secondary outcome

- Quality of life, aversion and nausea, measured with the EORTC QLQc30 and EORTC QLQ - LC13
- Number of unscheduled appointments with the dietitian.

Study description

Background summary

Lung cancer is the fourth most common type of cancer in The Netherlands, of which 80% is Non Small Cell Lung Cancer (NSCLC). NSCLC Patients are treated with chemoradiation or radiotherapy alone. At diagnosis, 20-45% of all patients have unintended weightloss, which can be even worse during treatment. Weightloss and undernutrition associated with complications and treatment outcome, worse physical functioning and decreased quality of life. Decreased physical functioning and decreased functional capacity are also related to a higher mortality.

Research on physical functioning, nutritional status and functional capacity and the relation between these variables in lung cancer patients is lacking.

Study objective

The primary goal of this study is to gain insight changes in components of nutritional status and functional capacity over time.

The objective is to improve the multidisciplinary health care for lung cancer patients.

Secondary goals are to investigate:

1. Which components of nutritional status measured at baseline are related to functional capacity at the end of medical treatment (chemoradiation or radiation)
2. Which components of nutritional status and functional capacity measured at the end of the medical treatment with chemoradiation or radiation are related to self-reported physical functioning and quality of life at 3 and 6 months after initial medical treatment.
3. The number of unscheduled appointments with the dietitian with patients treated for NSCLC with chemo(radiation).

Study design

This study is a prospective observational study.

Study burden and risks

Completing of questionnaires and undergoing non-invasive measurements.

Contacts

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Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

All patients 18 years or older with stage II or III NSCLC

Exclusion criteria

Patients with a pacemaker

Patients that don't speak Dutch

Patients with physical limitations who cannot be measured

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Health services research

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 10-07-2018

Enrollment: 100

Type: Actual

Ethics review

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|--------------------|------------------|
| Approved WMO | |
| Date: | 14-06-2018 |
| Application type: | First submission |
| Review commission: | METC NedMec |
| Approved WMO | |
| Date: | 02-05-2019 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO | |
| Date: | 14-08-2020 |
| Application type: | Amendment |
| Review commission: | METC NedMec |

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 |
|----------|----------------|
| CCMO | NL64289.031.17 |