# ELDAPT: Elderly with locally advanced Lung cancer: Deciding through geriatric Assessment on the oPtimal Treatment strategy

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Developing a clinically applicable geriatric screening instrument to stratify medically fit patients who may benefit from intensified treatment strategies and frail patients who will undergo best supportive care (which may include palliative RT), (2...

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

## Summary

### ID

NL-OMON54768

**Source**
ToetsingOnline

**Brief title**
ELDAPT

### Condition

- Respiratory and mediastinal neoplasms malignant and unspecified
- Respiratory tract neoplasms

**Synonym**
geriatric, Lung cancer

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Nederlandse Vereniging van artsen voor Longziekten en Tuberculose
**Source(s) of monetary or material Support:** Astra Zeneca,KWF

## Intervention

**Keyword:** Elderly, Geriatric, Lung cancer, Treatment

## Outcome measures

### Primary outcome

Quality-adjusted survival (QAS)

### Secondary outcome

• To perform geriatric assessment in stage III NSCLC patients to select

patients fit enough to undergo intensified treatment

• To identify reliable elements of the geriatric assessment that are predictive

for treatment tolerance and QAS in elderly patients with stage III NSCLC

• To determine the predictive value of saliva biomarkers with respect to

treatment tolerance and QAS in elderly patients with stage III NSCLCTo develop

and validate a clinically applicable geriatric screening instrument that

enables appropriate treatment stratification in the elderly NSCLC patient

• To compare different treatment strategies in fit elderly patients with

respect to

o Overall survival

o Quality adjusted survival

• To compare cost-effectiveness of different treatment strategies for fit

elderly patients with stage III NSCLC

# Study description

### Background summary

Lung cancer is a problem of the elderly: 30% of the lung cancer patients are aged >= 75 years. Due to underrepresentation of elderly patients in clinical trials there is a lack of evidence to select the optimal treatment strategy for these patients. Concurrent radiochemotherapy (RCHT) has been recognised as the standard treatment of stage III NSCLC patients with a good performance status. Evidence for this treatment was gained in clinical trials that mostly excluded elderly patients. Furthermore, the survival gain obtained with combined RCHT, comes with a significant increase in toxicity. Therefore, information on benefits and harms of intensified treatment with concurrent RCHT among a subpopulation of medically fit elderly patients is still lacking. Moreover, reliable tools are needed to distinguish the subgroup of fit patients from frail patients, i.e. those expected to experience important toxicity.

### Study objective

Developing a clinically applicable geriatric screening instrument to stratify medically fit patients who may benefit from intensified treatment strategies and frail patients who will undergo best supportive care (which may include palliative RT), (2) collecting evidence on the treatment with the highest QAS and (3) evaluation and clinical implementation of the project results, including a flow chart for safe and cost-effective clinical decision-making, in clinical practice.

• To perform geriatric assessment in stage III NSCLC patients to select patients fit enough to undergo intensified treatment
• To identify reliable elements of the geriatric assessment that are predictive for treatment tolerance and QAS in elderly patients with stage III NSCLC
• To determine the predictive value of saliva biomarkers to treatment tolerance and QAS in elderly patients with stage III NSCLCTo develop and validate a clinically applicable geriatric screening instrument that enables appropriate treatment stratification in the elderly NSCLC patient
• To compare different treatment strategies in fit elderly patients with respect to
o Overall survival
o Quality adjusted survival
• To compare cost-effectiveness of different treatment strategies for fit elderly patients with stage III NSCLC

### Study design

A multicentre, non-randomized intervention study. All registered patients will

undergo a geriatric assessment to determine the vulnerability. After this the registered patients will be followed (short questionnaires) to compare different treatment strategies (competitor CHRT, sequential CHRT and Radical RT) in elderly patients.

**Intervention**

All registered patients will have an initial geriatric assessment to assess vulnerability.

**Study burden and risks**

The burden associated with participation in this study consists of undergoing an extensive geriatric screening (time burden ± 1,5 hours) and the filling in of questionnaires (time burden ± 10 minutes, 1 month after treatment, 3 monthly the first year after treatment, 6 monthly the 2nd year, and yearly thereafter until 5 years after treatment). Optional saliva samples for biomarker analysis will be taken twice, at standard hospital visits. Site visits and physical examinations will be performed according to standard treatment.

# Contacts

**Public**
Stichting NVALT Studies

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Elderly (65 years and older)

## Inclusion criteria

Patients with any subtype of NSCLC, primary UICC Stage III, age >= 75 years.

## Exclusion criteria

- No NSCLC
- Primary UICC stage is not III
- younger than 75 years

# Study design

## Design

**Study type:** Observational non invasive

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|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Treatment |

## Recruitment

NL

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| Recruitment status: | Recruiting |
| Start date (anticipated): | 16-06-2016 |
| Enrollment: | 288 |
| Type: | Actual |

# Ethics review

Approved WMO

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| Date: | 24-02-2016 |

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| Application type: | First submission |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |
| Approved WMO Date: | 20-03-2017 |
| Application type: | Amendment |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |
| Approved WMO Date: | 08-11-2017 |
| Application type: | Amendment |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |
| Approved WMO Date: | 14-03-2018 |
| Application type: | Amendment |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |
| Approved WMO Date: | 31-07-2019 |
| Application type: | Amendment |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |
| Approved WMO Date: | 12-08-2022 |
| Application type: | Amendment |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |
| Approved WMO Date: | 22-08-2023 |
| Application type: | Amendment |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |
| Approved WMO Date: | 29-05-2024 |
| Application type: | Amendment |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |

# 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 |
|---|---|
| ClinicalTrials.gov | NCT02284308 |
| CCMO | NL51281.068.14 |