# A randomised phase III study comparing induction chemotherapy to daily low dose Cisplatin both combined with high dose radiotherapy in patients with inoperable non-small cell lung cancer stage I, II and III

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
09/01/2006		Protocol		
<b>Registration date</b> 09/01/2006	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	Individual participant data		
12/08/2009	Cancer			

## Plain English summary of protocol

Not provided at time of registration

## Contact information

## Type(s)

Scientific

#### Contact name

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## Additional identifiers

EudraCT/CTIS number

**IRAS** number

### ClinicalTrials.gov number

#### Secondary identifying numbers

NTR514; M 03 IVC/CKTO 2003-04

# Study information

#### Scientific Title

#### Study objectives

Concurrent chemoradiation is superior to sequential chemoradiation.

#### Ethics approval required

Old ethics approval format

## Ethics approval(s)

Received from local medical ethics committee

#### Study design

Multicentre randomised open label controlled parallel group trial

#### Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied

Lung cancer

#### Interventions

Randomisation of sequential versus concurrent chemoradiotherapy

#### Intervention Type

Other

#### Phase

Phase III

## Primary outcome measure

- 1. Disease-free survival
- 2. Local control
- 3. Pattern of recurrence.

#### Secondary outcome measures

- 1. Acute and late toxicity
- 2. Quality of Life.

#### Overall study start date

30/05/2003

#### Completion date

30/05/2006

# **Eligibility**

#### Key inclusion criteria

- 1. Pathologically confirmed non-small cell lung cancer (NSCLC)
- 2. Medically inoperable or irresectable NSCLC T 1-4, N0-3, M0
- 3. Age >18 years
- 4. Weight loss <10% in the last 3 months
- 5. FeV1 >0.99l, TLCO >59%

#### Participant type(s)

Patient

#### Age group

Adult

#### Lower age limit

18 Years

#### Sex

**Not Specified** 

#### Target number of participants

100

#### Key exclusion criteria

- 1. Previous chemotherapy and/or radiotherapy of the chest
- 2. Superior Vena cava syndrome
- 3. Hemoptysis causing a decrease of the blood haemoglobin of >1 mmol/l within 24 hours
- 4. Pleural or pericardial effusion (except if negative cytology)
- 5. Uncontrolled infection
- 6. Maximal length of the esophagus receiving 40 Gy of more than 18 cm, or maximal length of the esophagus receiving 66 Gy of more than 12 cm
- 7. Serious medical risk factors involving any of the major organ systems which may prevent adherence to the treatment schedule
- 8. Patients with pre-existant fibrotic lung disease
- 9. Creatinine clearance <70 ml/min or creatinine >1.25 x normal value

- 10. Bone marrow hypoplasia (Hb 6.8 mmol/l, WBC  $4 \times 10^9$ /l, platelets  $100 \times 10^9$ /l)
- 11. Recent myocardial infarction(<6 months) or evidence of heart failure
- 12. Impossibility to limit the spinal cord dose to a maximum of 50 Gy
- 13. Impossibility to exclude 2/3 of the heart from the boost volume

#### Date of first enrolment

30/05/2003

#### Date of final enrolment

30/05/2006

## Locations

#### Countries of recruitment

Netherlands

#### Study participating centre Academic Medical Center

Amsterdam Netherlands 1100 DD

# Sponsor information

#### Organisation

Netherlands Cancer Institute, Antoni van Leeuwenhoek Hospital (NKI/AVL) and Academic Medical Centre (AMC) (Netherlands)

#### Sponsor details

Plesmanlaan 121 Amsterdam Netherlands 1066 CX

#### Sponsor type

Hospital/treatment centre

#### **ROR**

https://ror.org/03xqtf034

# Funder(s)

## Funder type

#### Funder Name

Committee for Applied Clinical Research (Commissie voor Klinisch Toegepast Onderzoek [CKTO]) (Netherlands)

## **Results and Publications**

#### Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

Not provided at time of registration

#### **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2007		Yes	No