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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 x 10^9/l, platelets 100 x 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

Research council

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