A randomized multicenter study of carboplatin-gemcitabine versus carboplatin-paclitaxel in elderly patients with non-small cell lung cancer with emphasis on geriatric assessment and quality of life:
The NVALT-3 study.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26629

Source
NTR

Brief title
Chemotherapy in elderly patients

Health condition

Non Small Lungcancer (NSCLC) (NLD: Niet Kleincellig Longcarcinoom).

Sponsors and support

Primary sponsor: NVALT
Source(s) of monetary or material Support: Eli Lilly BV, The Netherlands
Amgen, The Netherlands

Intervention

Outcome measures

Primary outcome

To compare changes in quality of life between the two treatment groups from baseline as compared with quality of life at 18 weeks after start treatment.

Secondary outcome

1. Toxicity of both treatment arms;

2. Response rate in each treatment arm;

3. Survival of both treatment arms (overall survival, median survival, 1 year survival as well as progression free survival);

4. Geriatric assessments and serial assessments of quality of life and looking at:

a. Are there determinants in the CGA that could be used as a tool to predict which patients benefit from chemotherapy in terms of improvement in quality of life and experienced toxicity;

b. Is there a correlation between the GFI and the Karnofsky score and/or performance score according to WHO?;

c. Is there a correlation between GFI and toxicity of therapy?;

d. Is there a correlation between GFI and response to therapy?;

e. Is there a difference in baseline scores in CGA/GFI in patients accepting chemotherapy between an university hospital or general hospital? (indication for referral filter);

f. Does tumor response correlate with (changes in) global quality of life?;

5. The utilization of health care resources will be prospectively studied by counting the number of hospital days.

Study description

Background summary

In this phase III study we want to determine which platinum-based treatment is optimal in elderly patients (=/>70 years) having advanced NSCLC. Therefore we compare carboplatin-paclitaxel with carboplatin-gemcitabine to a maximum of 4 cycles and assess both regimens in terms of quality-of-life, toxicity, response rate and especially geriatric assessments. Our hypothesis is that elderly NSCLC patients are able to tolerate polychemotherapy and show improvement after this treatment. We will perform a complete geriatric assessment to evaluate whether these tests can be used as a tool to predict which patient will benefit from chemotherapy.

Study objective

Gemcitabine-carboplatin is better tolerable than paclitaxel-carboplatin in elderly patients having advanced NSCLC as assessed with quality of life questionnairs.

Study design

N/A

Intervention

Arm 1: Carboplatin AUC 5 mg/ml/min on day 1 - gemcitabine 1250 mg/m2 on days 1 and 8 of a three week cycle, for a maximum of 4 cycles.

Arm 2: Carboplatin AUC 5 mg/ml/min on day 1 - paclitaxel 175 mg/m2 on day 1 of a three week cycle, for a maximum of 4 cycles.

Carboplatin dose will be calculated according to the Calvert formula
Pretreatment a comprehensive geriatric assessment (CGA) will be performed by a specialized research nurse.

Contacts

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Eligibility criteria

Inclusion criteria

1. Histologically or cytologically confirmed inoperable (stage III) or disseminated (stage IV) non small cell lung cancer;

2. No previous chemo- and or radiotherapy;

3. Age =/> 70 years;

4. WHO performance status =/< 2;

5. Estimated life-expectancy of concomitant diseases for at least six months;

6. Measurable disease on physical examination, chest X-ray, or CT-scan;

7. Adequate bone marrow reserve: Leukocytes =/> 3.0 x 109/L, neutrophils =/> 1.5 x 109/L, platelets =/> 100 x 109/L;

8. Adequate renal function: creatinine clearance =/> 50 mL/min (Cockcroft formula);

9. Adequate liver function: serum aspartate aminotransferase (ASAT/SGOT) and serum alanine aminotransferase (ALAT/SGPT) less than 1.5 times the upper normal limit for the institution, total serum bilirubin within the normal limits for the institution, alkaline phosphatase less than 5 times the upper normal limit for the institution (unless bone metastases are present in the absence of any liver disease);

10. Patients must understand the study, be willing to comply with the scheduled visits and give written informed consent before starting the study.

Exclusion criteria

1. Patients with a mixed form of NSCLC and SCLC;

2. Active uncontrolled infection;

3. Presence of CNS metastases;

4. Symptomatic sensory peripheral neuropathy =/> grade 1 according to NCIC Common Toxicity Criteria;

5. Patients with uncorrected hypercalcemia;

6. Unstable peptic ulcer, unstable diabetes mellitus or other contraindications for the use of corticosteroids;

7. Unstable cardiac conditions;

8. Concomitant administration to any other experimental drugs under investigation.

However, patients should continue on their usual medications.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2003
Enrollment:	182
Type:	Actual

Ethics review

Positive opinion

Date:	05-03-2007

Application type: First submission

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
NTR-new	NL901
NTR-old	NTR925
Other	: N/A
ISRCTN	incomplete

Study results

Summary results
N/A