Docetaxel and Carboplatin once every 3 weeks versus weekly Docetaxel in advanced non-small cell lung cancer: a Multicenter phase III study from the Dutch Chest Physician Association.

No registrations found.

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

Summary

ID

NL-OMON28184

Source
Nationaal Trial Register

Brief title
NVALT-1 study

Health condition

Non small cell lung cancer (NSCLC)

Sponsors and support

Primary sponsor: UMCG
Department Pulmonary Diseases
Source(s) of monetary or material Support: Aventis Pharma

Intervention

Outcome measures

Primary outcome

The primary endpoint of the study is the overall survival.

Secondary outcome

Secondary endpoints are:

1. To assess efficary in terms of response rates, time to progression, duration of response and duration of palliation (appendix 5);

2. To evaluate toxic effects of treatment (CTC criteria, appendix 2);

3. To evaluate the effect of therapy on Quality of Life (appendix 5).

Study description

Background summary

This is a phase III study to determie overall survival in patients with advanced (stage-IIIb pleuritis carcinomatosa and stage IV) non-small cell lung cancer (NSCLC) treated with docetaxel 75 mg/m2 and carboplatin (dose = GFR x 6) once every 3 weeks for 5 cycles (arm 1) or docetaxel 35 mg/m2 every week for 6 consecutive weeks followed with 2 rest weeks for 3 cycles (arm 2). Treatment will be continued until patient has received a total of 5 respectively 3 cycles of until disease progression or intolerable toxicity has occurred, or if the patient wants to withdraw from treatment. Quality of life will be measured before the start of treatment, at week 6, 12, 16, 24 and week 30.
A total of 440 patients are required to find relevant survival differences.

Study objective

In this study we compare in patients with advanced NSCLS a platinum contaiing chemotherapy regimen with a prolonged dose-intensified regimen with docetaxel that appeared to be less toxic.

Study design

N/A

Intervention

In arm 1 docetaxel will be administered at a dose of 75 mg/m2 as a one-hour i.v. infusion followed by carboplatin administered as a 30 min i.v. infusion on day 1 of each 3 week cycle. The carboplatin dose can be calculated as follows: carboplatin dose = 6 x (glomerular filtration rate + 25).

In arm 2 docetaxel will be administered weekly at a dose of 35 mg/m2 for 6 weeks, followed by 2 rest weeks.

Eight weeks is one cycle. Treatment will continue till the patient has received a total of 5 cycles in arm 1 or 3 cycles in arm 2, until progression or intolerable toxicity occurs or when the patient wants to withdraw from treatment.

Quality of life will be measured before the start of treatment, at week 6, 12, 16, 24 and week 30. Quality of Life will be measured with a standardized and validated questionnaire, i.e. EORTC-QLQ-30 and LC-13 (appendix 5). The questionnaire will be sent by mail.

Contacts

Public
University Medical Center Groningen (UMCG), Department of Pulmonary Disease,
Box 30001
H.J.M. Groen
Groningen 9700 RB
The Netherlands
+31 (0)50 3616161
Scientific
University Medical Center Groningen (UMCG), Department of Pulmonary Disease,
Box 30001
H.J.M. Groen
Groningen 9700 RB
The Netherlands
+31 (0)50 3616161

Eligibility criteria

Inclusion criteria

1. Histological or cytological diagnosis of unresectable (stage III-b, pleuritis carcinomatosa) or disseminated (stage IV) NSCLS;

2. Age ≥ 18 years;

3. No prior chemotherapeutic treatment for NSCLC;

4. Measurable or evaluable tumor on physical examination, chest X-ray, CT-scan;

5. Performance status 0-2 (ECOG-score, see appendix 1);

6. Prior radiotherapy is allowed as long as no more than 25% of red bone marrow was irradiated. The irradiated area is not the only source of measurable disease;

7. Estimated life expectancy of at least 12 weeks;

8. Adequate bone marrow reserve: leukocytes ≥ 3,0 x 10^9/L, neutrophils ≥ 1,5 x 10^9/L, platelets 100 ≥ 10^9/L, and hemoglobin ≥ 6,2 mmol/L;

9. Adequate renal function (serum creatinine ≤ 130 µmol/L or creatinine clearance ≥ 60 ml/min);

10. Adequate liver function (total bilirubin ≤ UNL, ALAT/SGTP and ASAT/SGOT < 2,0 x UNL, alkaline phosphatase < 5,0 x UNL for the institution (UNL = Upper Normal Limit);

11. Patients of childbearing age should take medically approved contraceptive precautions during the trial and 3 months afterwards;

12. Patients must be able to comply with the scheduled visits;

13. Patients must give written informed consent before starting the study.

Exclusion criteria

1. Other serious diseases, such as heart failure, angina pectoris, myocardial infarction within the last 6 months, uncontrolled hypertension, active infection or significant psychiatric illness;

2. Symptomatic brain metastases;

3. Patients with uncorrected hypercalcemia;

4. Patients with peripheral polyneuropathy grade ≥ 2 CTC Criteria;

5. Patients with a second primary malignancy except carcinoma in situ of the cervix or adequately treated basas cell carcinomas of the skin or adequately treated upper respiratory tract malignancies, disease-free more than 1 year after treatment;

6. ASAT and ALAT > 1,5 x UNL and alkaline phosphatase > 2,5 x UNL;

7. Patients who are pregnant or breast-feeding;

8. Participation in other trial with investigational drug.

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):	26-06-2000
Enrollment:	440
Type:	Actual

Ethics review

Positive opinion

Date:	13-01-2009
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	NL689
NTR-old	NTR1627
Other	NVALT/RP : 0001/56976
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A