

A randomised phase II study of pemetrexed compared to pemetrexed-carboplatin in pretreated patients with advanced non-small cell lung cancer

Submission date 11/04/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 11/04/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 05/01/2021	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Study website

<http://www.nvalt-oncology.nl>

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

A randomised phase II study of pemetrexed compared to pemetrexed-carboplatin in pretreated patients with advanced non-small cell lung cancer

Acronym

NVALT-7 study

Study objectives

Is retreatment with platin based regimen in patients with recurrence of Non-Small Cell Lung Cancer (NSCLC) who failed platin based regimen in the first line more beneficial?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Study design

Randomised, active controlled, parallel group, multicentre trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Non Small Cell Lung Cancer (NSCLC)

Interventions

Experimental arm A:

Pemetrexed 500 mg/m² plus carboplatin Area Under the concentration–time Curve (AUC) 5 on day one every 21 days.

Control arm B:
Pemetrexed 500 mg/m² on day one every 21 days.

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

Pemetrexed, carboplatin

Primary outcome measure

To compare time to progression between single agent pemetrexed and pemetrexed-carboplatin in patients who failed previous cytotoxic treatment for NSCLC locally advanced and metastatic disease stage IIIB and IV.

Secondary outcome measures

1. To characterise the quantitative and qualitative toxicities of both regimens, response rates and duration of response for responding patients, and survival
2. Pharmacogenetic biomarker assessment

Overall study start date

22/09/2005

Completion date

01/01/2008

Eligibility

Key inclusion criteria

1. Histologically or cytologically confirmed NSCLC locally advanced and metastatic disease stage IIIB and IV, with evidence of disease progression after cytotoxic treatment which should have included a platinum agent
2. At least three months from prior chemotherapy with complete recovery from first line chemotherapy side effects to less than grade two
3. At least one unidimensionally measurable lesion meeting Response Evaluation Criteria in Solid Tumours (RECIST) criteria
4. Eastern Cooperative Oncology Group (ECOG) performance status zero to two
5. Aged greater than 18 years
6. Adequate organ function, including:
 - a. adequate bone marrow reserve: Absolute Neutrophil Count (ANC) greater than $1.5 \times 10^9/L$, platelets greater than $100 \times 10^9/L$
 - b. hepatic: bilirubin less than 1.5 x Upper Limit of Normal (ULN), Alkaline Phosphatase (AP), Alanine Aminotransferase (ALT), Aspartate Aminotransferase (AST) less than 3.0 x ULN. AP, ALT, and AST less than 5 x ULN is acceptable if the liver has tumour involvement
 - c. renal: calculated creatinine clearance greater than 45 ml/min based on the Cockcroft and Gault formula
7. Signed informed consent
8. Male and female patients with reproductive potential must use an approved contraceptive

method, if appropriate. Female patients with childbearing potential must have a negative serum pregnancy test within seven days prior to study enrolment

9. Estimated life expectancy greater than 12 weeks

10. Patient compliance and geographical proximity that allow adequate follow up

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

Target number of participants

230

Key exclusion criteria

1. Pregnant or lactating women
2. Patients who are poor medical risks because of non-malignant disease as well as those with active uncontrolled infection
3. Documented brain metastases unless the patient has completed local therapy for central nervous system metastases and has been off corticosteroids for at least two weeks before enrolment
4. Concomitant treatment with any other experimental drug under investigation
5. Inability to interrupt aspirin or other nonsteroidal anti-inflammatory agents for a five-day period (eight day period for long-acting agents such as piroxicam)
6. Inability or unwillingness to take folic acid, vitamin B-12 supplementation or dexamethasone

Date of first enrolment

22/09/2005

Date of final enrolment

01/01/2008

Locations**Countries of recruitment**

Netherlands

Study participating centre

Vrije Universiteit Medical Centre (VUMC)

Amsterdam

Netherlands

1007 MB

Sponsor information

Organisation

VU University Medical Centre (The Netherlands)

Sponsor details

Department of Pulmonary Diseases

P.O. Box 7057

Amsterdam

Netherlands

1007 MB

Sponsor type

Hospital/treatment centre

Website

<http://www.vumc.nl/english/#http://www.vumc.nl/english/>

ROR

<https://ror.org/00q6h8f30>

Funder(s)

Funder type

Industry

Funder Name

Eli Lilly (The Netherlands)

Funder Name

Roche Nederland BV (The 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	01/07/2016	04/01/2021	Yes	No