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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

Registration date
11/04/2007

Overall study status
Completed

Last Edited
05/01/2021

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Non Small Cell Lung Cancer (NSCLC)

Interventions
Experimental arm A:
Pemetrexed 500 mg/m^2 plus carboplatin Area Under the concentration–time Curve (AUC) 5 on day one every 21 days.

Control arm B:
Pemetrexed 500 mg/m^2 on day one every 21 days.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Pemetrexed, carboplatin

Primary outcome(s)
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.

Key secondary outcome(s))
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

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 leasion 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 x 10^9/L, platelets greater than 100 x 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 Cockroft 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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Not Specified

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)

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

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
Study website	Study website	11/11/2025	11/11/2025	No	Yes