ISRCTN78329606 https://doi.org/10.1186/ISRCTN78329606

A phase II study of erlotinib and bevacizumab in patients with locally advanced and/or metastatic (stage IIIB or IV) non-small cell lung cancer who have not received prior chemotherapy

Submission date	Recruitment status	[_] Prospectively registered
20/02/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/02/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
26/03/2021	Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof H J M Groen

Contact details
University Medical Centre Groningen (UMCG)
Department of Pulmonary Disease
PO Box 30001
Groningen
Netherlands
9700 RB
+31 (0)50 361 6161
h.j.m.groen@int.umcg.nl

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
NTR528

Study information

Scientific Title
A phase II study of erlotinib and bevacizumab in patients with locally advanced and/or metastatic (stage IIIB or IV) non-small cell lung cancer who have not received prior chemotherapy

Study objectives
Tumour response from erlotinib and bevacizumab as first line treatment in advanced Non-Small Cell Lung Cancer (NSCLC) will result in non-progressive disease within six weeks in more than 50% of patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
An open label, multicentre, phase II study

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
All patients will receive:
1. Erlotinib 150 mg/day orally
2. Bevacizumab 15 mg/kg every three weeks as a 90 minutes infusion

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Erlotinib and bevacizumab

Primary outcome(s)

Efficacy of erlotinib and bevacizumab in first line treatment of NSCLC as determined by the rate of no progression at six weeks.

Key secondary outcome(s))
Efficacy of erlotinib and bevacizumab as determined by:
1. The objective response rate
2. Duration of response
3. Time to disease progression or death
4. Survival
5. Safety of erlotinib and bevacizumab

Completion date
01/01/2008

Eligibility

Key inclusion criteria
1. Cytologically or histologically advanced non-squamous NSCLC. Patients with squamous cell histology are eligible only if their intrathoracic disease has been completely resected, they have no current evidence of intrathoracic disease (with the exception of isolated pleural effusion), and they have not had haemoptysis in the 28 days prior to randomisation
2. No prior chemotherapy or therapy with systemic anti-tumor therapy (e.g., monoclonal antibody therapy) or prior exposure to agents directed at the Human Epidermal growth factor Receptor (HER) axis (e.g. Epidermal Growth Factor Receptor Tyrosine Kinase [EGFR TK] inhibitors, Herceptin). Prior surgery and/or localised irradiation is permitted provided that the irradiated lesion is not the only measurable lesion
3. Measurable disease as defined by Response Evaluation Criteria In Solid Tumors (RECIST) criteria
4. Age 18 or greater
5. Eastern Cooperative Oncology Group (ECOG) performance status of zero to two
6. Life expectancy of at least 12 weeks
7. At least four weeks since any prior surgery or radiotherapy. Patients who, in the opinion of the investigator, have fully recovered from surgery in less than four weeks may also be considered for the study. Patients must have recovered (Common Toxicity Criteria [CTC] less than or equal to one) from acute toxicities of any previous therapy
8. Neutrophils more than or equal to 1.5 x 10^9/L and platelets more than 100 x 10^9/L
9. Serum bilirubin less than or equal to 1.5 x Upper Limit of Normal (ULN). Aspartate aminotransferase (ASAT)/Alanine aminotransferase (ALAT) less than or equal to 2.5 x ULN (in case of liver metastases less than or equal to 5 x ULN), Alkaline phosphatase less than or equal to 2.5 x ULN
10. Serum creatinine less than or equal to 1.5 x ULN or creatinine clearance more than or equal to 60 ml/min
11. Urine dipstick for proteinuria less than 2+. Patients discovered to have more than or equal to 2+ proteinuria on dipstick urinalysis at baseline, should undergo a 24-hour urine collection and must demonstrate less than or equal to 1 g of protein/24hr
12. Normal serum calcium
13. Able to comply with study and follow-up procedures
14. Able to take oral medication
15. For all females of childbearing potential a negative pregnancy test must be obtained within

48 hours before registration starting therapy
16. Patients with reproductive potential must use effective contraception
17. Written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
47

Key exclusion criteria
1. Any unstable systemic disease (including active infection, uncontrolled hypertension, unstable angina, congestive heart failure, myocardial infarction within the previous year, severe cardiac arrhythmia requiring medication, hepatic, renal or metabolic disease)
2. Evidence of tumour invading major blood vessels
3. Major surgical procedure, open biopsy or significant traumatic injury within 28 days prior to day zero (patients must have recovered from any major surgery), or anticipation of need for major surgical procedure during the course of the study
4. Planned radiotherapy for underlying disease (prior completed radiotherapy treatment allowed)
5. Serious non-healing wound or ulcer
6. Evidence of bleeding diathesis or coagulopathy. Presence of a cavitary lesion or evidence of tumor invading or abutting major blood vessels
7. Brain metastasis or spinal cord compression that is newly diagnosed and/or has not yet been treated with surgery and/or radiation; previously diagnosed and treated Central Nervous System (CNS) metastases or spinal cord compression with evidence of stable disease for at least two months is permitted
8. Patients who cannot take oral medication, who require intravenous alimentation, have had prior surgical procedures affecting absorption, or have active peptic ulcer disease
9. History of haemorrhagic disorders
10. Current or recent (within ten days prior to study treatment start) ongoing treatment with anticoagulants for therapeutic purposes i.e. except for anticoagulation for maintenance of patency of permanent indwelling Intravenous (IV) catheters
11. History of more than or equal to grade two haemoptysis (symptomatic and medical intervention indicated)
12. Ongoing treatment with aspirin (more than 325 mg/day) or other medications known to predispose to gastrointestinal ulceration
13. Nursing mothers

Date of first enrolment
01/01/2006

Date of final enrolment
01/01/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
University Medical Centre Groningen (UMCG)
Groningen
Netherlands
9700 RB

Sponsor information

Organisation
University Medical Centre Groningen (UMCG) (The Netherlands)

ROR
https://ror.org/03cv38k47

Funder(s)

Funder type
Industry

Funder Name
Roche

Alternative Name(s)
F. Hoffmann-La Roche Ltd, F. Hoffmann-La Roche & Co, F. Hoffmann-La Roche AG, Roche Holding AG, Roche Holding Ltd, Roche Holding, Roche Holding A.G., Roche Holding, Limited, F. Hoffmann-La Roche & Co., Roche Holdings, Inc.

Funding Body Type
Government organisation

Funding Body Subtype

For-profit companies (industry)

Location
Switzerland

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/03/2011	26/03/2021	Yes	No