ISRCTN92263269 https://doi.org/10.1186/ISRCTN92263269

A phase I/II randomised study of Tarceva® (erlotonib), used concurrently with thoracic radiation in patients with advanced non-small cell lung cancer

Submission date
13/10/2008

Registration date
16/01/2009

Last Edited
13/10/2017

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

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
MAST1006

Study information

Scientific Title

Tarceva® (erlotonib), used concurrently with thoracic radiation in patients with advanced non-small cell lung cancer: a phase I/II open-label randomised controlled trial

Acronym
TACTICAL

Study objectives
To explore the use of concurrent radiotherapy and an oral tablet called erlotinib (an epidermal growth factor inhibitor) for the treatment of advanced non-small cell lung cancer and assess whether combination therapy improves response and overall survival compared to radiotherapy alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands Research Ethics Committee, approval pending as of 13/10/2008, ref: 08/H1208/41

Study design
Phase I: Interventional open-label single-centre trial
Phase II: Open-label randomised controlled multi-centre trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Non-small cell lung cancer (NSCLC)

Interventions
Phase I: All 18 patients will receive erlotonib 150 mg orally (po) once daily. This will be combined with radiotherapy consisting of an initial radiation dose of 30 Gy/10 factions (3 Gy, 5 days per week, 2 weeks) for the first 6 patients, with a view to dose escalation to 36 Gy/12 fractions with two further groups of 6 patients depending on observed dose limiting toxicity levels.

Phase II: Radiotherapy will be administered to all patients at the optimal dose determined in Phase 1 - either 30 Gy/10 fractions or 36 Gy/12 fractions. Half of patients will also receive erlotinib 150 mg po, once daily. Erlotinib and follow-up will continue after the radiotherapy until disease progression or the development of grade 3 or 4 toxicity despite dose reduction.

Follow-up: Each subject is followed for 12 weeks including pre-treatment and treatment visits, then monthly for 6 months if there is no progression and then annually until progression.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Erlotonib (Tarceva®)

Primary outcome(s)
Phase I: Evaluation of early safety and efficacy of erlotinib by determining the maximum tolerated dose in combination with external beam radiotherapy
Phase II: Evaluation of disease control rate at 6 months

Key secondary outcome(s))
1. Objective response rate, assessed by Response Evaluation Criteria in Solid Tumors (RECIST) at baseline, 6 weeks after radiotherapy treatment (Visit 9, Week 9) and 6 months.
2. Duration of response
3. Time to progression
4. Time to distant failure
5. Overall survival
6. Safety

Completion date
31/12/2010

Eligibility

Key inclusion criteria
Patients (both males and females) with non-small cell lung cancer (NSCLC) with:
1. Histologically or cytologically confirmed non-small cell lung cancer
2. Unresectable stage III or metastatic disease suitable for fractionated palliative radiotherapy
3. One dimensionally measurable disease
4. No prior radiotherapy for this cancer
5. Forced expiratory volume in 1 second (FEV1) >1
6. Performance status less or equal to 2
7. Adequate haematologic function
8. Serum creatinine concentration >1.5 x upper limit or normal (ULN) and /or EDTA clearance >60 ml/min
9. Bilirubin level <1.5 x ULN
10. Age 18-80 years
11. Females of child bearing potential must agree to comply with effective contraceptive measures

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
80 years

Sex
All

Key exclusion criteria
Patients with non-small cell lung cancer must not meet any of the following:
1. Previous radiotherapy for non-small cell lung cancer
2. Concurrent treatment with other experimental drugs
3. Past or current history of other neoplasms, except a) curatively treated non-melanoma skin cancer or b) adequately treated in-situ cancer of the cervix or c) other cancer curatively treated and with no evidence of disease for at least 5 years
4. Significant cardiac disease, clinical congestive cardiac failure, cardiac arrhythmia, uncontrolled hypertension or recent history of myocardial infarction/ischaemia
5. Serious intercurrent medical or psychiatric illness, including serious active infection
6. Pregnant or nursing women

Date of first enrolment
01/01/2009

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Hammersmith Hospital
London
United Kingdom
W12 0HS

Sponsor information

Organisation
Imperial College Healthcare NHS Trust (UK)

ROR
https://ror.org/056ffv270

Funder(s)

Funder type
Industry

Funder Name
Roche Products Limited (UK) (ref: MO21781)

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?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes