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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	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 16/01/2009	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 13/10/2017	**Condition category** Cancer	[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
01/01/2009

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
Phase I: 18; Phase II: 80 (total: 98)

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
England

United Kingdom

Study participating centre
Hammersmith Hospital
London
United Kingdom
W12 0HS

Sponsor information

Organisation
Imperial College Healthcare NHS Trust (UK)

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Sponsor type
Hospital/treatment centre

Website
http://www.imperial.nhs.uk

ROR
https://ror.org/056ffv270

Funder(s)

Funder type
Industry

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

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?
HRA research summary			28/06/2023	No	No