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Capecitabine and erlotinib in advanced lung cancer

Submission date	Recruitment status	[_] Prospectively registered
14/01/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/01/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/09/2017	Cancer	

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
2008-007317-79

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CCR3176

Study information

Scientific Title
A phase 1b trial of the combination of CAPecItabine and Tarceva in Advanced Lung Cancer

Acronym
CAPITAL

Study objectives
That the combination capecitabine and erlotinib is safe, tolerable, and active in patients with metastatic non-small cell lung cancer, to be considered for further testing in phase 2 clinical trials.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Ethics Committee at the Royal Marsden NHS Foundation Trust, 16/10/2009, ref: 09 /H0806/52

Study design
Phase 1b clinical trial

Primary study design
Interventional

Secondary study design
3+3 dose escalation design

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
Metastatic non-small cell lung cancer with adenocarcinoma histology, in the second line setting

Interventions
Escalating doses of capecitabine (mg/sq.m, p.o., b.i.d.) and erlotinib (mg, p.o., daily) will be given on a 3-weekly cycle.

Intervention Type
Drug

Phase

Phase I

Drug/device/biological/vaccine name(s)
1. Capecitabine (Xeloda) 2. Erlotinib (Tarceva)

Primary outcome measure
To determine the safety, tolerability and maximum tolerated dose of capecitabine when given in combination with erlotinib and to establish a dose limiting toxicity dose schedule for the combination.

Secondary outcome measures
Preliminary assessment of the efficacy of capecitabine when given in combination with erlotinib. Efficacy will be measured by assessment of response rates, progression-free survival, and overall survival.

Overall study start date
01/03/2010

Completion date
30/10/2014

Eligibility

Key inclusion criteria
1. Histologically confirmed diagnosis of NSCLC of adenocarcinoma sub-type. Mixed histological features are excluded
2. Progressing disease by radiological criteria
3. Any stage not fit for radical treatment
4. Age ≥ 18 years
5. ECOG performance status 0-2 and predicted life expectancy ≥ 12 weeks
6. Adequate haematopoietic, hepatic and renal function defined as follows: Absolute neutrophil count (ANC) ≥1.5 x 10^9/L and platelet count ≥100 x 10^9/L Bilirubin ≤1.5 x ULN, ALT (SGPT) ≤2.5 x ULN (or ≤ 5 x ULN in cases of liver metastases) Serum creatinine clearance ≥50 ml/min
7. Patients must provide verbal and written informed consent to participate in the study
8. Use of an acceptable contraception for men and women of childbearing potential

For part 1 of the protocol (2nd-line patients), all the general inclusion criteria (above) must be met. In addition the following must be met:
1. Previous treatment with systemic chemotherapy (one line only for non-adjuvant / radical treatment)
2. Recovery from any treatment related toxicities regardless of regimen prior to registration, except for alopecia, grade 2 fatigue, or grade 1 neurotoxicity

For part 2 of the protocol (1st-line patients), all the general inclusion criteria must be met. In addition the following must be met:
1. Unsuitable for platinum-based doublet chemotherapy

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
It is expected that a maximum overall total of 40 patients will be enrolled (anticipated 28 to first part and 12 to second part)

Key exclusion criteria
1. Any concurrent anticancer systemic therapy
2. If the administration of erlotinib to patients receiving concomitant CYP3A4 or CYP1A2 inducers/inhibitors could impact significantly on their clinical care, these patients should be excluded- see Appendix 1
3. Prior treatment with any EGFR-directed inhibitor
4. Systemic chemotherapy, radiotherapy to a target lesion, or investigational anti-cancer treatment within 28 days of commencing treatment
5. Any other active malignancies unless deemed cured with at least 3 years of follow-up. In situ cervical cancer and in situ/basal cell skin cancer are permitted
6. Active or uncontrolled infections or serious illnesses or medical conditions that could interfere with the patients ongoing participation in the study
7. History of psychiatric condition that might impair the patients ability to understand or to comply with the requirements of the study or to provide informed consent
8. Gastro-intestinal abnormalities, including inability to take oral medication, requirement for intravenous feeding, active peptic ulcer, prior surgical procedures affecting absorption, any medical co-morbidity affecting gastrointestinal absorption
9. Patients on steroids must have been on that dose for at least 3 weeks
10. Pregnant women, or those currently breastfeeding

Date of first enrolment
18/03/2010

Date of final enrolment
28/10/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Marsden NHS Foundation Trust - Sutton
Downs Road
Sutton

Surrey
United Kingdom
SM2 5PT

Study participating centre
Royal Marsden NHS Foundation Trust
Fulham Road
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London
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SW3 6JJ

Sponsor information

Organisation
Royal Marsden NHS Foundation Trust

Sponsor details
Downs Road
Sutton
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/0008wzh48

Funder(s)

Funder type
Industry

Funder Name
F Hoffman-La Roche Ltd (UK)

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2016		Yes	No
HRA research summary			28/06/2023	No	No