

A randomised, placebo-controlled trial of Tarceva (OSI-774, erlotinib) in patients with advanced non-small cell lung cancer unsuitable for chemotherapy

Submission date 19/01/2004	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 25/02/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 19/10/2018	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English Summary

<http://cancerhelp.cancerresearchuk.org/trials/a-trial-looking-at-a-new-biological-therapy-for-advanced-non-small-cell-lung-cancer>

Contact information

Type(s)

Scientific

Contact name

Dr Siow-Ming Lee

Contact details

Consultant Medical Oncologist
Meyerstein Institute of Oncology
Middlesex and UCL Hospitals
Mortimer Street
London
United Kingdom
W1N 8AA
+44 (0)20 7380 9091
sm.lee@uclh.org

Additional identifiers

EudraCT/CTIS number

2004-000729-31

IRAS number

ClinicalTrials.gov number
NCT00275132

Secondary identifying numbers

N/A

Study information

Scientific Title

A randomised, placebo-controlled trial of Tarceva (OSI-774, erlotinib) in patients with advanced non-small cell lung cancer unsuitable for chemotherapy

Acronym

TOPICAL

Study hypothesis

Erlotinib may stop the growth of tumour cells by blocking some of the enzymes needed for cell growth. It is not yet known whether erlotinib is more effective than a placebo in treating non-small cell lung cancer (NSCLC).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Multicentre Research Ethics Committee (MREC), 04/05/2004, ref: 04/6/032

Study design

Randomised controlled 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 below to request a patient information sheet

Condition

Non-small cell lung cancer (NSCLC)

Interventions

Patients are randomised to one of two treatment arms with 1:1 randomisation:

Arm 1: Tarceva (OSI-774, erlotinib) PO (by mouth) 150 mg daily up to 24 months.

Arm 2: Matched placebo PO daily up to 24 months

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Erlotinib

Primary outcome measure

To compare the effect on survival of Tarceva compared to placebo in patients with advanced NSCLC not suitable for chemotherapy.

Secondary outcome measures

1. Progression free survival
2. Toxicity
3. Response rate
4. Quality of life
5. Cost-effectiveness

Overall study start date

01/04/2005

Overall study end date

31/01/2008

Eligibility

Participant inclusion criteria

1. Diagnosis within 62 days prior to randomisation (this criteria was added on the 12th June 2007)
2. Histologically or cytologically confirmed NSCLC
3. Advanced disease NSCLC (stage IIIb or IV)
4. Chemotherapy-naive patients
5. Patients considered unsuitable for chemotherapy, for example:*
- 5.1. Eastern Cooperative Oncology Group (ECOG) performance status two or three
- 5.2. ECOG performance status zero or one with a calculated creatinine clearance less than or equal to 60 ml/min (Cockcroft formula)
6. Aged 18 years or over
7. Estimated life expectancy of at least 8 weeks
8. Able to take oral medication
9. Using effective contraception if of reproductive potential (women of child bearing potential must have a negative pregnancy test performed by a healthcare professional prior to

randomisation)

10. Willing and able to give informed consent

11. Willing to participate in the biological study

* examples given do not imply that all such patients are unsuitable for chemotherapy - patients should be considered individually

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

664

Participant exclusion criteria

1. Previous treatment with any biological anti-cancer therapy (e.g. Iressa, thalidomide, cetuximab)
2. Prior chemotherapy
3. Prior palliative radiotherapy (except to bone metastases, within the last 2 weeks)
4. Pregnant or lactating women
5. Evidence of other significant laboratory finding or concurrent uncontrolled medical illness which in the opinion of the investigator would interfere with protocol treatment or results comparison or render the subject at high risk from treatment complications. Examples include:
 - 5.1. Severe uncontrolled infection
 - 5.2. Cardiovascular: unstable angina, myocardial infarction within 1 month
 - 5.3. Gastro-intestinal: uncontrolled inflammatory bowel disease (e.g. Crohn's or ulcerative colitis)
 - 5.4. Hepatic:
 - 5.4.1. Serum bilirubin more than or equal to 2 x Upper Limit of Normal (ULN)
 - 5.4.2. Serum transaminases more than or equal to 2 x ULN in the absence of liver metastases, or more than or equal to 5 x ULN with liver metastases
 - 5.5. Renal:
 - 5.5.1. Acute renal failure
 - 5.5.2. Serum creatinine more than or equal to 5 x ULN
6. Other previous or current malignant disease likely to interfere with protocol treatment or comparisons
7. Symptomatic brain metastases
8. Current treatment with Cox II inhibitor

Recruitment start date

01/04/2005

Recruitment end date

31/01/2008

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Middlesex and UCL Hospitals

London

United Kingdom

W1N 8AA

Sponsor information

Organisation

University College London (UK)

Sponsor details

Gower Street

London

England

United Kingdom

WC1E 6BT

Sponsor type

University/education

ROR

<https://ror.org/02jx3x895>

Funder(s)

Funder type

Charity

Funder Name

Cancer Research UK (CRUK) (UK) (ref: C1438/A4147)

Alternative Name(s)

CR_UK, Cancer Research UK - London, CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Funder Name

London Lung Cancer Group (UK) (Charity no. 1074994)

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?
Plain English results				No	Yes
Results article	results	01/11/2012		Yes	No
Results article	cost-effectiveness results	02/07/2015		Yes	No