

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

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

## Plain English summary of protocol

<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

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### Contact details

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## Additional identifiers

Clinical Trials Information System (CTIS)

2004-000729-31

**ClinicalTrials.gov (NCT)**

NCT00275132

**Protocol serial number**

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 objectives**

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

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

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(s)**

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

**Key secondary outcome(s)**

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

**Completion date**

31/01/2008

## **Eligibility**

**Key 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 (Cockroft 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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key 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

**Date of first enrolment**

01/04/2005

**Date of final enrolment**

31/01/2008

**Locations**

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Middlesex and UCL Hospitals**

London

United Kingdom

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# Sponsor information

## Organisation

University College London (UK)

## 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, Cancer Research UK (CRUK), 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

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/11/2012		Yes	No

<a href="#">Results article</a>	cost-effectiveness results	02/07/2015	Yes	No
<a href="#">Plain English results</a>			No	Yes