ISRCTN77383050 https://doi.org/10.1186/ISRCTN77383050

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

Registration date
25/02/2004

Last Edited
19/10/2018

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00275132

Clinical Trials Information System (CTIS)
2004-000729-31

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
W1N 8AA

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