

A trial to see if a body protein called ERCC1 affects how people with advanced non small cell lung cancer respond to different types of chemotherapy

Submission date 02/10/2008	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/11/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 20/01/2022	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

<http://www.cancerhelp.org.uk/trials/trial-to-see-if-protein-ercc1-affects-how-people-with-advanced-non-small-cell-lung-cancer-respond-different-types-chemotherapy>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

2007-007639-17

ClinicalTrials.gov (NCT)

NCT00801736

Protocol serial number

UCL/07/158

Study information

Scientific Title

A multicentre, randomised, phase III trial of platinum-based chemotherapy versus non-platinum chemotherapy, after excision repair cross-complementation group 1 (ERCC1) protein stratification, in patients with advanced/metastatic non-small cell lung cancer (NSCLC)

Acronym

ET Trial

Study objectives

The trial will have two main objectives:

1. To detect an improvement in survival for ERCC1 positive patients treated with a non-platinum chemotherapy compared to platinum-based treatment
2. To establish non-inferiority or improvement in survival for ERCC1 negative patients treated with a platinum-based chemotherapy compared to non-platinum treatment

Secondary objectives:

1. To examine progression-free survival, response rate and quality of life between the two treatment regimens, according to ERCC1 status
2. To investigate whether the treatment effect differs according to:
 - 2.1. Histology (squamous versus non-squamous)
 - 2.2. Gender (males versus females)
 - 2.3. Performance status
3. To undertake a cost-effectiveness analysis based on all patients, and according to ERCC1 status

As of 22/02/2011 the anticipated end date for this trial has been updated from 30/11/2011 to 31/12/2014

Ethics approval required

Old ethics approval format

Ethics approval(s)

Charing Cross Research Ethics Committee, 24/09/2008, ref: 08/H0711/45

Study design

A multicentre, randomised, phase III trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Stage IIIb or IV non-small cell lung cancer (NSCLC)

Interventions

Patients are randomised to one of two treatment arms:

Arm A: cisplatin/pemetrexed (cisplatin 75 mg/m² over one hour/pemetrexed 500 mg/m² over 10 minutes - intravenous [IV] administration)

Arm B: paclitaxel/pemetrexed (paclitaxel 175 mg/m² over three hours/pemetrexed 500 mg/m² over 10 minutes - IV administration)

Patients will receive up to six cycles of treatment; all patients are assessed with each cycle of chemotherapy. The first post-chemotherapy visit should be completed 3 - 4 weeks after last chemotherapy cycle. Assessments will then be monthly until one year from the date of first chemotherapy cycle, then two-monthly thereafter.

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Pemetrexed, cisplatin, paclitaxel

Primary outcome(s)

Survival:

1. To detect an improvement in survival for ERCC1 positive patients treated with a non-platinum chemotherapy compared to platinum-based treatment
2. To establish non-inferiority or improvement in survival for ERCC1 negative patients treated with a platinum-based chemotherapy compared to non-platinum treatment

Key secondary outcome(s)

1. Progression-free survival and response rate using RECIST
2. Quality of life - European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC-QLQ C30) with additional lung cancer questions (LC 13) and EuroQol EQ-5D
3. Cost-effectiveness analysis - assessing trial medication use, management of adverse events, if other anti-cancer treatments used, assessing hospital admission episodes (in-patient nights) and day case visits, community-based support (e.g. visits to and from GP or nurse; time in hospice)

Completion date

31/12/2017

Eligibility

Key inclusion criteria

1. Histologically confirmed NSCLC
2. Have a tissue biopsy available for sending to the central laboratory to determine ERCC1 status
3. Presentation with stage IIIb (not amenable to curative treatment) or IV disease staging scans must be no more than 28 days prior to randomisation. Patients with relapsed NSCLC must not

have received prior chemotherapy or biological therapy (previous surgery or radical radiotherapy allowed).

4. At least one measurable lesion according to Response Evaluation Criteria in Solid Tumours (RECIST)

5. Either sex, at least 18 years of age

6. Eastern Cooperative Oncology Group (ECOG) performance status 0 - 1

7. Estimated life expectancy of at least 8 weeks

8. Adequate bone marrow function as evidenced by the following (assessed within 14 days of starting treatment):

8.1. Absolute neutrophil count (ANC) equal or more than $1.5 \times 10^9/L$

8.2. Platelet count equal or more than $75 \times 10^9/L$

8.3. Haemoglobin equal or more than 9 g/dL

9. Adequate liver function as evidenced by the following (assessed within 14 days of starting treatment):

9.1. Total bilirubin equal or less than 1.5 x upper limit of normal (ULN)

9.2. Aspartate transaminase (AST) equal or less than 3 x ULN or equal or less than 5 x ULN is acceptable with liver metastases

9.3. Alanine transaminase (ALT) equal or less than 3 x ULN

10. Adequate renal function as evidenced by the following (assessed within 14 days of starting treatment):

10.1. Glomerular filtration rate (GFR) greater than 50 ml/min as measured by ethylenediaminetetraacetic acid (EDTA), or

10.2. GFR greater than 60 ml/min as measured by the Cockcroft and Gault formula

11. Previous palliative radiotherapy to non-target metastatic lesions is allowed (not in the 28 days prior to randomisation)

12. Patients with stable brain metastases will be allowed to enrol. Stable brain metastases being defined as no progression of brain metastases 28 days after treatment as documented by a computed tomography (CT) scan/magnetic resonance image (MRI) of the brain. Patients with incidentally discovered asymptomatic brain metastases may be enrolled and treated with trial chemotherapy without prior brain irradiation if deemed feasible by the treating physician.

13. Signed informed consent form

14. Use of effective contraception during, and for 6 months after trial treatment by patients of reproductive potential and partners of reproductive potential. Patients who receive aprepitant (anti-emetic) must be willing to use an alternative or back-up method to hormonal contraceptives as aprepitant may reduce their efficacy.

15. Female patients with childbearing potential must have a negative serum pregnancy test prior to randomisation

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Cytologically or clinically diagnosed NSCLC
2. Evidence of significant medical condition or laboratory finding which, in the opinion of the treating physician or chief investigator, makes it undesirable for the patient to participate in the trial, e.g.:
 - 2.1. Congestive heart failure
 - 2.2. Myocardial infarction within 6 months
 - 2.3. Significant neurological or psychiatric disorders that would impact trial participation
 - 2.4. Infection requiring intravenous (I.V.) antibiotics
 - 2.5. Tuberculosis with ongoing therapy at trial entry
 - 2.6. Superior vena cava syndrome, except if controlled with radiation
 - 2.7. Active peptic ulcer disease
 - 2.8. Uncontrolled diabetes mellitus
 - 2.9. Any contraindication to high dose corticosteroid therapy such as herpes simplex, herpes zoster, hepatitis, or other disease
3. Presence of uncontrolled brain or leptomeningeal metastases thought to require immediate radiotherapy
4. Presence of clinically significant third-space fluid collections (for example, ascites or pleural effusions) that cannot be controlled by drainage or other procedures prior to trial entry
5. Unable to interrupt aspirin or other non-steroidal anti-inflammatory drugs (NSAIDs)
6. Unable or unwilling to take vitamin B12 and folic acid
7. A history of prior malignant tumour, unless the patient has been without evidence of disease for at least 3 years or the tumour was a non-melanoma skin tumour or early cervical cancer
8. Pregnant or lactating women
9. Inability to comply with protocol or trial procedures

Date of first enrolment

02/10/2009

Date of final enrolment

24/07/2013

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

University College Hospital

235 Euston Road

Fitzrovia

London

United Kingdom

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Sponsor information

Organisation

University College London (UK)

ROR

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

Funder(s)

Funder type

Industry

Funder Name

Eli Lilly and Company

Alternative Name(s)

Lilly, Eli Lilly & Company, Eli Lilly & Co., Eli Lilly And Co, Eli Lilly & Co

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United States of America

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2017		Yes	No
Results article	results	01/10/2019	10/09/2019	Yes	No

[Basic results](#)
[Plain English results](#)

20/01/2022 No No
 No Yes