# A two-arm randomised controlled trial of concurrent chemo-radiotherapy comparing twice-daily and once-daily radiotherapy schedules in patients with limited stage Small Cell Lung Cancer (SCLC) and good performance status

Submission date 17/09/2007	<b>Recruitment status</b> No longer recruiting	<ul><li>[X] Prospectively registered</li><li>[X] Protocol</li></ul>
Registration date 08/10/2007	<b>Overall study status</b> Completed	<ul><li>[] Statistical analysis plan</li><li>[X] Results</li></ul>
Last Edited 16/06/2021	<b>Condition category</b> Cancer	Individual participant data

#### Plain English summary of protocol

https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-to-find-the-bestway-to-give-radiotherapy-for-people-with-small-cell-lung-cancer

#### Study website

http://www.christie.nhs.uk/research-division/researchers/disease-groups/lung/convert.aspx

### **Contact information**

**Type(s)** Scientific

**Contact name** Dr Helen Bradley

#### **Contact details**

Manchester Clinical Trials Unit The University of Manchester Room 1.316, Jean McFarlane Building Oxford Road Manchester United Kingdom M13 9PL +44 0161 306 8239 helen.bradley@manchester.ac.uk

### Additional identifiers

EudraCT/CTIS number

**IRAS number** 

ClinicalTrials.gov number NCT00433563

Secondary identifying numbers 06-DOG07-68

## Study information

#### Scientific Title

A two-arm randomised controlled trial of concurrent chemo-radiotherapy comparing twice-daily and once-daily radiotherapy schedules in patients with limited stage Small Cell Lung Cancer (SCLC) and good performance status

#### Acronym

CONVERT

#### Study objectives

This study aims to establish a standard chemo-therapy regimen for patients with limited stage Small Cell Lung Cancer (SCLC) and good performance status.

**Ethics approval required** Old ethics approval format

**Ethics approval(s)** UK ethics approval on 21/12/2007

**Study design** Multicentre randomised active-controlled parallel-group unblinded phase III trial

**Primary study design** Interventional

**Secondary study design** Randomised controlled trial

**Study setting(s)** Hospital

**Study type(s)** Treatment

#### Participant information sheet

http://www.christie.nhs.uk/media/209035/Patient\_info.pdf

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

Limited stage small cell lung cancer

#### Interventions

Control arm:

1. Between 4 and 6 cycles of cisplatin and etoposide (cisplatin 25 mg/m^2 intravenous [iv] day 1 - 3 or 75 mg/m^2 day 1, etoposide 100 mg/m^2 iv day 1 - 3)

2. Concurrent twice daily (BD) radiotherapy 45 Gy, 30 twice-daily fractions over 3 weeks, 5 days per week from day 22 of cycle 1

3. Prophylactic Cranial Irradiation (PCI) will be given if indicated

Experimental arm:

1. Between 4 and 6 cycles of cisplatin and etoposide (cisplatin 25 mg/m^2 iv day 1 - 3 or 75 mg/m^2 day 1, etoposide 100 mg/m^2 iv day 1 - 3)

2. Concurrent once daily (OD) radiotherapy 66 Gy in 33 daily fractions over 6.5 weeks, 5 days per week from day 22 of cycle 1

3. Prophylactic Cranial Irradiation (PCI) will be given if indicated

Patients will undergo screening examinations and will then be randomised to a treatment arm. Treatment will begin within 2 weeks of randomisation. During chemoradiotherapy treatment the patient will be assessed prior to each cycle via physical exam and blood tests, with chest X-rays prior to cycles 1, 3 and 5. Research staff will monitor any toxicities and record treatment and toxicity details on a Case Report Form (CRF). The patient will be seen again within 4 weeks of the final cycle for assessment, response to treatment will be evaluated and prophylactic cranial irradiation given if indicated. The patient will then enter the follow-up phase of the study - during follow-up patients will be seen at 3 monthly intervals for 12 months, and six monthly thereafter until death.

#### Intervention Type

Drug

**Phase** Phase III

**Drug/device/biological/vaccine name(s)** Cisplatin, etoposide

#### Primary outcome measure

Overall survival.

Information for each of the primary and secondary objectives will be gained by assessing the patient prior to each cycle of chemotherapy, at a completion visit within 4 weeks of the final cycle, and then at follow-up visits which are 3 monthly for the first year, then six monthly thereafter until death.

#### Secondary outcome measures

- 1. Local progression-free survival
- 2. Metastasis-free survival
- 3. Common Terminology Criteria for Adverse Events version 3.0 (CTCAE v3.0) toxicity
- 4. Chemotherapy dose intensity
- 5. Radiotherapy dose intensity

Information for each of the primary and secondary objectives will be gained by assessing the patient prior to each cycle of chemotherapy, at a completion visit within 4 weeks of the final cycle, and then at follow-up visits which are 3 monthly for the first year, then six monthly thereafter until death.

#### Overall study start date

15/12/2005

#### **Completion date**

15/02/2019

## Eligibility

#### Key inclusion criteria

1. Either sex, aged greater than or equal to 18 years

2. Estern Cooperative Oncology Group (ECOG) Performance Status (PS) grade 0 - 1. Patients with PS 2 whose general condition is explained by obstructive/bulky disease likely to improve after the first cycle of chemotherapy can be included at the discretion of the local investigator.

Patients with PS 2 as a result of comorbid conditions will be excluded

3. Histologically or cytologically confirmed SCLC

4. No patients with mixed small-cell and non-small-cell histologic features

5. No history of previous malignancy in the last 5 years (except non melanomatous skin or in-situ cervix carcinoma). Patients with previous malignancies (except breast cancer) and in remission for at least 5 years can be included

6. Limited stage disease (Veterans Administration Lung Cancer Study Group), i.e., patients whose disease can be encompassed within a radical radiation portal

7. No pleural or pericardial effusions proven to be malignant

8. Radiotherapy (RT) target volume acceptable by the local radiotherapist

9. Pulmonary function:

9.1. Forced Expiratory Volume in one second (FEV1) greater than 1 litre or 40% predicted value 9.2. Carbon Monoxide Transfer Coefficient (KCO) (Carbon Monoxide Diffusing capacity in the whole Lung per unit Alveolar Volume [DLCO/VA]) greater than 40% predicted

10. Maximum of one of the following adverse biochemical factors:

10.1. Serum alkaline phosphatase more than 1.5 times the Upper Limit of Normal (ULN)

- 10.2. Serum sodium less than lower limit of normal
- 10.3. Serum lactate dehydrogenase (LDH) greater than upper limit of normal (added 09/04/2008) 11. Normal serum creatinine and calculated creatinine clearance greater than or equal to 50 ml /min. If calculated creatinine clearance is less than 50 ml/mn according to the Cockroft and Gault

formula, an Ethylenediaminetetraacetic Acid (EDTA) clearance should be performed 12. Adequate haematological function:

12.1. Neutrophils greater than 1.5 x 10^9/l

12.2. Platelets greater than 100 x 10^9/l

13. No other previous or concomitant illness or treatment which in the opinion of the clinician will interfere with the trial treatments or comparisons

14. No prior surgical resection of the primary tumour, no prior radiotherapy for lung cancer

15. Considered fit to receive any of the trial regimens

16. Female patients must satisfy the investigator that they are not pregnant, or are not of childbearing potential, or are using adequate contraception. Men must also use adequate contraception, as etoposide is clastogenic

17. Patients must not be breastfeeding

18. Patient has read the patient information sheet and has signed the consent form

19. Patients available for follow-up

### Participant type(s)

Patient

### Age group

Adult

**Lower age limit** 18 Years

### Sex

Both

**Target number of participants** 532

**Total final enrolment** 547

**Key exclusion criteria** Does not comply with the above inclusion criteria.

Date of first enrolment 07/04/2008

Date of final enrolment 29/11/2013

## Locations

**Countries of recruitment** Belgium

Canada

England

France

Netherlands

Poland

Slovenia

Spain

United Kingdom

**Study participating centre The Christie NHS Foundation Trust** Manchester United Kingdom M20 4BX

### Sponsor information

**Organisation** Christie Hospital NHS Foundation Trust

Sponsor details Wilmslow Road Manchester England United Kingdom M20 4BX the-christie.sponsoredresearch@nhs.net

**Sponsor type** Hospital/treatment centre

Website http://www.christie.nhs.uk/

ROR https://ror.org/03v9efr22

## Funder(s)

**Funder type** Charity

**Funder Name** Cancer Research UK 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

### **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 Plain English results	Details	Date created	Date added	<b>Peer reviewed?</b> No	<b>Patient-facing?</b> Yes
<u>Protocol article</u>	protocol	20/01/2016		Yes	No
<u>Results article</u>	sub-study results	01/05/2017		Yes	No
Results article	results	01/08/2017		Yes	Νο
Results article	secondary results	01/03/2019		Yes	No