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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	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 08/10/2007	**Overall study status** Completed	
Last Edited 16/06/2021	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-to-find-the-best-way-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

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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 child-bearing 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

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