ISRCTN12155469 https://doi.org/10.1186/ISRCTN12155469

IDEAL-CRT: A Phase I/II trial of concurrent chemoradiation with dose-escalated radiotherapy in patients with stage II or stage III non-small cell lung cancer

Submission date
26/10/2009

Recruitment status
No longer recruiting

Registration date
30/11/2009

Overall study status
Completed

Last Edited
24/03/2022

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
http://www.cancerhelp.org.uk/trials/a-trial-different-doses-radiotherapy-with-chemotherapy-non-small-cell-lung-cancer-ideal-crt

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

UCL/08/0201

Study information

Scientific Title
A phase I/II multicentre interventional trial of concurrent chemoradiation with dose-escalated radiotherapy in patients with stage II or stage III non-small cell lung cancer

Acronym
IDEAL-CRT

Study objectives
The aim of IDEAL-CRT is to investigate the toxicity, feasibility and potential clinical effectiveness of dose-escalated radiotherapy (RT) with concurrent chemotherapy in stage IIb or stage III non-small cell lung cancer (NSCLC) as a potential experimental arm in future phase III trials. It will also allow the assessment and validation of radiobiological models for predicting tumour control and normal tissue complications.

Please note, as of 03/11/2011 updates have been made to the trial record and can be found under this date in the relevant fields below.
Both start and end dates for this trial have been updated. The dates at time of registration were as follows:
Original start date: 01/12/2009
Original end date: 01/12/2011

Ethics approval required
Old ethics approval format

Ethics approval(s)
Hammersmith and Queen Charlotte's and Chelsea Research Ethics Committee on 27/07/2009 (ref: 09/H0707/38)

Study design
Phase I/II multicentre interventional study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Non-small cell lung cancer

Interventions
Dose escalation will be through an individual patient-based model, associated with an acceptable level of grade 3 toxicity (from oesophagus or lung).

Radiotherapy (30 single daily fractions to planning target volume [PTV]) for six weeks given concurrently with standard chemotherapy (2 cycles of cisplatin and vinorelbine).

On-treatment assessments:
1. Weekly for 6 weeks

Post-treatment assessments:
2. Weekly until 1 month post RT, then
3. Monthly until 6 months post RT, then
4. 3-monthly until 2 years post RT, then
5. 6-monthly until 3 years post RT, then
6. Annually

Intervention Type
Drug

Phase
Phase I/II

Drug/device/biological/vaccine name(s)
Cisplatin, vinorelbine

Primary outcome measure
Current primary outcome measures as of 03/11/2011:
Oesophagitis:
Grade 2-5 according to Common Terminology Criteria for Adverse Events v4.0 (CTCAE v4.0 - appendix 1) acute oesophagitis during RT or within 3 months from the first dose of RT for all patients.

Pneumonitis:
Early Radiation Pneumonitis (ERTP) determined by grade 2 - 5 according to CTCAE v4.0 toxicity rates occurring within 6 months from the first dose of RT for all patients.

Previous primary outcome measures:
Oesophagitis:
Grade 2 - 5 according to Common Terminology Criteria For Adverse Events v4.0 (CTCAE v4.0) acute oesophagitis during RT or within 6 months from the first dose of RT rate for all patients. In IDEAL-CRT this will be used for 6 months post-RT.

Secondary outcome measures
Current secondary outcome measures as of 03/11/2011:
Oesophagus:
Chronic oesophageal stricture rate: grade 1 - 5 according to Radiation Therapy Oncology Group (RTOG) late toxicity scales from 3 months post-RT for all patients.

Lung:
1. Pneumonitis grades 2 - 5 (CTCAE v4.0) 6 or more months after end of RT for all patients
2. Changes from baseline in FEV1, forced vital capacity (FVC) and DLCO (CTCAE v4.0 grades 2 - 5)
3. Any grade 2 - 5 pulmonary toxicity according to CTCAE v4.0 from start of RT to death

Previous secondary outcome measures:
3. Any grade 2 - 5 pulmonary toxicity according to CTCAE v4.0 from start of RT to 12 months post-RT

Overall study start date
01/10/2010

Completion date
31/03/2015

Eligibility

Key inclusion criteria
1. Histologically or cytologically confirmed NSCLC
2. Stages: IIa, IIb, IIIa and IIIb (according to International Union Against Cancer Classification of Malignant Tumors [UICC TNM] 7th Edition 2009) (Stage IIa added as of 03/11/2011)
3. World Health Organization (WHO) performance status 0 or 1
4. Life expectancy greater than 6 months
5. Inoperable disease as assessed by a lung cancer multi-disciplinary team (MDT); or operable but MDT agrees that chemoradiotherapy (chemoRT) is a suitable alternative to surgery; or operable but the patient refuses surgery
6. Radiotherapy dose constraints consistent with minimum prescription dose of 63 Gy in 30 fractions
7. Age 18 or over (no upper age limit), either sex
8. No prior thoracic radiotherapy
9. No prior lobectomy/pneumonectomy
10. No prior systemic chemotherapy
11. Willing and able to give informed consent
12. Adequate pulmonary function test (PFT) results:
12.1. Forced expriatory volume in one second (FEV1) greater than or equal to 40% of predicted, or greater than or equal to 1 litre
12.2. Diffusing capacity of the lung for carbon monoxide (DCLO) greater than or equal to 40% of predicted
13. For women with childbearing potential:
13.1. Negative pregnancy test
13.2. Adequate contraceptive precautions during the trial and for 3 months after trial treatment
14. Haematology and biochemistry baselines suitable for cisplatin/vinorelbine chemotherapy
15. Renal function adequate for chemotherapy greater than or equal to 60 ml/min. If glomerular filtration rate (GFR) less than 60 ml/min (Cockroft & Gault-Appendix 7), check GFR with EDTA clearance or equivalent
Added 03/11/2011:
16. In the clinician's view the patient is fit to tolerate the trial treatment without exceptional risk of complications or likelihood of re-planning

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
105

Key exclusion criteria
1. Radiotherapy dose constraints not consistent with minimum prescription dose of 63 Gy in 30 fractions
2. Clinically diagnosed NSCLC without cytological or histological evidence of non-small cell lung cancer
3. Previous or current malignant disease likely to interfere with the protocol treatment or comparisons
4. Upper lobe tumours if the brachial plexus is within the high-dose volume
5. Medically unstable (e.g. unstable diabetes, uncontrolled arterial hypertension, infection, hypercalcaemia, ischaemic heart disease)
6. Women of childbearing potential who are not practicing adequate contraceptive precautions
7. Women who are pregnant or lactating
8. Chronic liver disease and/or bilirubin greater than 35
9. Chronic renal disease and/or calculated creatinine clearance less than 60 ml/min
10. Connective tissue disorders (e.g. scleroderma, systemic lupus erythematosus)
11. Inability to comply with protocol or trial procedures
12. 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
Added as of 03/11/2011:
13. Patients presenting with a collapsed lung or collapse of an entire lobe
14. In the clinician's view there is an exceptional risk of complications or likelihood of re-planning associated with the trial treatment for this patient

Date of first enrolment
01/10/2010

Date of final enrolment
31/03/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Guy's & St. Thomas' NHS Trust
London
United Kingdom
SE1 7UH

Sponsor information

Organisation
University College London (UCL) (UK)

Sponsor details
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WC1E 6BT

Sponsor type
University/education

Website
http://www.ucl.ac.uk/

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (CRUK) (UK) (ref: C13530/A10424)

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
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2016		Yes	No
Results article	long-term results	15/03/2020	21/04/2020	Yes	No
Plain English results			24/03/2022	No	Yes