

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

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|--|---|---|
| Submission date 26/10/2009 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 30/11/2009 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 24/03/2022 | Condition category Cancer | <input type="checkbox"/> 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

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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 expiratory 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 (DLCO) 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 (Cockcroft & 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

Gower Street
London
England
United Kingdom
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 |