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Phase I study of Continuous Hyperfractionated Accelerated RadioTherapy - Escalated Dose

Submission date	Recruitment status	[_] Prospectively registered
10/12/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
03/12/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
02/09/2022	Cancer	

Plain English Summary
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-adding-increased-dose-radiation-to-chart-radiotherapy-to-treat-non-small-cell-lung-cancer-chart-ed

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CHART-ED Version Final 2.0

Study information

Scientific Title
A dose escalation phase I study of continuous, hyperfractionated, accelerated radiotherapy (CHART) in patients with inoperable non-small cell lung cancer

Acronym
CHART-ED

Study hypothesis
The CHART-ED study aims to assess the feasibility of radiotherapy dose-escalation for treating patients with inoperable stage III non-small cell lung cancer (NSCLC).

This study is a multicentre phase I feasibility study. Once completed, a randomised phase II comparison of the dose escalated chemo-radiotherapy CHART-ED schedule with a concurrent chemo-radiotherapy protocol is planned.

As of 01/03/2011 the anticipated end date for this trial has been updated from 31/12/2009 to 01/09/2011

Ethics approval required
Old ethics approval format

Ethics approval(s)
Oxfordshire Research Ethics Committee (REC) A on 21/10/2008 (ref: 08/H0604/147)

Study design
Multicentre phase I feasibility study

Primary study design
Interventional

Secondary study design
Non randomised study

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

Condition
Non-small cell lung cancer (NSCLC)

Interventions

Pre-study evaluation:
The following baseline assessments need to be performed within the 42 days prior to the radiotherapy planning scan:
1. History (including severity of chronic obstructive airways disease) and examination
2. Respiratory related medication current and previous history
3. All concurrent medication (e.g., statins, angiotensin converting enzyme inhibitor [ACEI], non-steroidal anti-inflammatory drugs [NSAIDs])
4. Assessment of performance status
5. Assessment of MRC dyspnoea score
7. Chest X-ray (CXR)
8. Positron emission tomography (PET) or co-registered PET-computed tomography (PET-CT) scan
9. CT scan of the thorax and upper abdomen.
Either the CT scan and PET scan (or co-registered PET-CT scan) must be performed within 42 days of the radiotherapy (RT) planning scan.
10. Pulmonary function tests (PFTS) - performed within 14 days of the RT planning CT scan:
10.1. Forced expiratory volume in one second (FEV1)
10.2. Forced vital capacity (FVC)
10.3. Carbon monoxide transfer factor (DLCO) corrected for haemoglobin (Hb) level
11. Baseline blood tests:
11.1. Haematology: full blood count
11.2. Biochemistry: renal function, liver function, bone profile
12. Electrocardiogram (ECG)
13. Pregnancy test (if applicable)

Interventions:
Radiotherapy dose-escalation.

Dose escalation schedule:
Group 1: 57.6 Gy in 38 fractions, treating 8 hours apart on day 15
Group 2: 61.2 Gy in 40 fractions, treating 8 hours apart on days 15 - 16
Group 3: 64.8 Gy in 42 fractions, treating 8 hours apart on days 15 - 17

Intervention Type
Other

Phase
Phase I

Primary outcome measure
The degree of dose escalation achievable. This will be determined by the incidence and grade of potential dose limiting toxicities:
1. Pulmonary toxicity:
1.1. Early radiation pneumonitis (ERTP): occurring within 6 months of finishing RT
1.2. Late radiation pneumonitis (LRTP)/fibrosis: occurring after the six months period following RT
1.3. Changes in pulmonary function tests (PFTs)
2. Oesophageal toxicity:
2.1. Acute oesophagitis: occurring during RT or up to three months post RT
2.2. Chronic oesophagitis/stricture: occurring/persisting beyond three months post-completion of RT

3. Spinal cord toxicity
4. Cardiac toxicity

Toxicity will be assessed at the following post-treatment assessments:
1. Weekly until 1 month post-treatment
2. Monthly until 6 months post-treatment
3. Three-monthly until 2 years post-treatment
4. Six-monthly until 3 years post-treatment
5. Annually until 5 years post-treatment

Secondary outcome measures
1. Tumour response
2. Two year survival
3. Overall survival
4. Progression free survival
5. Local control

Follow-up visits measuring weight (performance status) and adverse events (dyspnoea score) will occur at the following timepoints:
1. Weekly until 1 month post-treatment
2. Monthly until 6 months post-treatment
3. Three-monthly until 2 years post-treatment
4. Six-monthly until 3 years post-treatment
5. Annually until 5 years post-treatment

In addition, the following investigations will be requested:
1. CXR: at months 1, 2, 5, 12, 18, 24 post-treatment
2. CT chest/abdomen: at months 3 and 6 post-treatment
3. PFTs: at months 3, 6 and 12 post-treatment
4. ECG: at months 6 and 12 post-treatment

Appropriate investigations and assessments will be performed if the patient becomes symptomatic in between trial follow-up appointments.

Overall study start date
01/01/2009

Overall study end date
01/09/2011

Eligibility

Participant inclusion criteria
Queries about inclusion criteria should be addressed prior to entry into the study. Patients are eligible for the study if all of the following criteria are met:
1. Histologically or cytologically confirmed stage III NSCLC
2. World Health Organization (WHO) performance status 0 or 1
3. Life expectancy greater than 6 months
4. Inoperable disease as assessed by a Lung Cancer Multi-Disciplinary Team (MDT) with input from Thoracic Surgeon; or operable but the patient refuses surgery
5. Aged 18 or over (no upper age limit), either sex

6. No prior thoracic radiotherapy
7. No prior lobectomy/pneumonectomy
8. No prior systemic chemotherapy
9. Willing and able to give informed consent
10. Adequate pulmonary function test (PFT) results: forced expiratory volume in one second (FEV1) and/or carbon monoxide transfer factor (DCLO) greater than or equal to 40% of predicted
11. For women with childbearing potential:
11.1. Negative pregnancy test
11.2. Adequate contraceptive precautions

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
10 - 36

Total final enrolment
18

Participant exclusion criteria
Patients are ineligible for the trial if any of the following criteria are met:
1. Previous or current malignant disease likely to interfere with the protocol treatment or comparisons
2. Medically unstable (e.g. unstable diabetes, uncontrolled arterial hypertension, infection, hypercalcaemia, cardiovascular disease such as congestive cardiac failure)
3. Previous diagnosis of interstitial lung disease
4. Previous diagnosis of spinal cord disease
5. Women of childbearing potential who are not practicing adequate contraceptive precautions
6. Women who are pregnant or lactating
7. Connective tissue disorders (e.g. scleroderma, systemic lupus erythematosus)

Recruitment start date
01/01/2009

Recruitment end date
01/09/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Weston Park Hospital
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Sponsor information

Organisation
Sheffield Teaching Hospitals NHS Foundation Trust (UK)

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Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/018hjpz25

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (CRUK) (UK) (ref: C9759/A9766)

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	01/03/2016		Yes	No
Plain English results			02/09/2022	No	Yes