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A randomised phase II/III trial of induction chemotherapy followed by Continuous Hyperfractionated Accelerated Radiotherapy (CHART) versus CHART alone in patients with inoperable non-small cell lung cancer

Submission date 02/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 21/09/2005	**Overall study status** Completed	
Last Edited 19/10/2018	**Condition category** Cancer	

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/a-trial-looking-at-chemotherapy-followed-by-chart-radiotherapy-or-chart-radiotherapy-alone-for-non-small-cell-lung-cancer

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2004-004438-15

IRAS number

ClinicalTrials.gov number
NCT00253591

Secondary identifying numbers
LU23

Study information

Scientific Title
A randomised phase II/III trial of induction chemotherapy followed by Continuous Hyperfractionated Accelerated Radiotherapy (CHART) versus CHART alone in patients with inoperable non-small cell lung cancer

Acronym
INCH

Study objectives
CHART has been shown to improve survival compared to conventional radical radiotherapy. In addition, the Non Small Cell Lung Cancer meta-analysis suggested a survival benefit with the addition of the chemotherapy to conventional radiotherapy. An important question therefore is whether the addition of chemotherapy to CHART might improve survival still further - adding chemotherapy might improve both local and distant control.

More details can be found at: http://www.ctu.mrc.ac.uk/research_areas/study_details.aspx?s=15

Ethics approval required
Old ethics approval format

Ethics approval(s)
Northern and Yorkshire MREC, 05/04/2005, REC ref: 04/MRE03/90

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Interventions
Please note that recruitment to this trial was closed earlier than planned on the 7th December 2007 (initial anticipated end date of recruitment: 12th July 2008) due to poor accrual. 46 patients have been randomised into this trial.

Control arm: CHART alone.
Radiotherapy schedule: 54 Gy in 36 fractions (3 times daily) over 12 consecutive days.

Experimental arm: Induction Chemotherapy followed by CHART. Chemotherapy schedule: 3 x 3 weekly cycles of Cisplatin (80 mg/m^2) on weeks 1, 4, 7, Vinorelbine (25 mg/m^2) on weeks 1, 2, 4, 5, 7 and 8 followed by 4-6 week interval from day 1 of final dose of Cisplatin then CHART (same as control arm).

Intervention Type
Drug

Phase
Phase II/III

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

Primary outcome measure
Overall survival

Secondary outcome measures
1. Progession-free survival
2. Response
3. Toxicity
4. Quality of Life
5. Tumour Control
6. Cost effectiveness

Overall study start date
01/05/2005

Completion date
30/05/2009

Eligibility

Key inclusion criteria
1. Histologically or cytologically confirmed stage I-III NSCLC, considered suitable for chemotherapy and CHART
2. Inoperable disease as assessed by a lung cancer MDT with thoracic surgical input

3. Previously untreated by chemotherapy or radiotherapy
4. Eastern Cooperative Oncology Group (ECOG) performance status 0 or 1
5. No prior or current malignant disease likely to interfere with protocol treatment

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
As of 14/12/2007: Closed to recruitment. 46 patients have been enrolled; Target number provided at time of registration: 500

Key exclusion criteria
1. Medically unstable (e.g. unstable diabetes, uncontrolled arterial hypertension, infection, hypercalcaemia or ischaemic heart disease
2. Previous or current malignant disease likely to interfere with protocol or comparisons
3. Women who are pregnant or lactating
4. Women of childbearing potential who are not practising adequate contraceptive precautions

Date of first enrolment
01/05/2005

Date of final enrolment
14/12/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Weston Park Hospital
Sheffield
United Kingdom
S10 2SJ

Sponsor information

Organisation
Medical Research Council (UK)

Sponsor details
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Sponsor type
Research council

ROR
https://ror.org/03x94j517

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (ref: C9759/A4591)

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
Results article	results	01/11/2011		Yes	No