

# 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

<b>Submission date</b> 02/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 21/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 19/10/2018	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## 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

### Contact name

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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](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<sup>2</sup>) on weeks 1, 4, 7, Vinorelbine (25 mg/m<sup>2</sup>) 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. Progression-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

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**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?
<a href="#">Plain English results</a>				No	Yes
<a href="#">Results article</a>	results	01/11/2011		Yes	No