ISRCTN63027630 https://doi.org/10.1186/ISRCTN63027630

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

**Contact name**
Dr Matthew Hatton

**Contact details**
Weston Park Hospital
Whitham Road
Sheffield
United Kingdom
S10 2SJ
+44 (0)114 226 5080
matthew.hatton@sth.nhs.uk

## Additional identifiers

**Clinical Trials Information System (CTIS)**
2004-004438-15

**ClinicalTrials.gov (NCT)**
NCT00253591

**Protocol serial number**
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

**Study type(s)**
Treatment

**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(s)
Overall survival

### Key secondary outcome(s))
1. Progession-free survival
2. Response
3. Toxicity
4. Quality of Life
5. Tumour Control
6. Cost effectiveness

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
All

### 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
United Kingdom

England

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

## Sponsor information

### Organisation
Medical Research Council (UK)

### 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, Cancer Research UK (CRUK), CRUK

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
Other non-profit organizations

**Location**
United Kingdom

# Results and Publications

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/11/2011 | | Yes | No |
| Plain English results | | | | No | Yes |