

A phase III randomised trial of sequential chemotherapy followed by radical radiotherapy versus concurrent chemo-radiotherapy followed by chemotherapy in patients with inoperable stage III Non-Small Cell Lung Cancer (NSCLC) and good performance status.

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|--|---|---|
| Submission date 13/02/2004 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 10/03/2004 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 19/10/2018 | Condition category Cancer | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

<http://cancerhelp.cancerresearchuk.org/trials/a-trial-to-find-the-best-timing-for-radiotherapy-and-chemotherapy-for-advanced-non-small-cell-lung-cancer>

Contact information

Type(s)

Scientific

Contact name

Dr Joseph Maguire

Contact details

Clatterbridge Centre for Oncology
Bebington
Wirral
Liverpool
United Kingdom
CH63 4JY

Additional identifiers

Clinical Trials Information System (CTIS)

2004-001920-19

ClinicalTrials.gov (NCT)

NCT00309972

Protocol serial number

N/A

Study information

Scientific Title

A phase III randomised trial of sequential chemotherapy followed by radical radiotherapy versus concurrent chemo-radiotherapy followed by chemotherapy in patients with inoperable stage III Non-Small Cell Lung Cancer (NSCLC) and good performance status.

Acronym

SOCCAR - Sequential Or Concurrent Chemotherapy And Radiotherapy

Study objectives

The aim of this trial is to compare concurrent treatment to sequential treatment, to see which works better for advanced Non-Small Cell Lung Cancer (NSCLC).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Central Manchester LREC, 30/09/2004, REC ref: 04/Q1407/256

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Non Small Cell Lung Cancer (NSCLC)

Interventions

Patients will be randomised to sequential or concurrent chemotherapy and radiotherapy:

1. Sequential arm - patients receive 4 x 21 day cycle of vinorelbine and cisplatin, followed by radical radiotherapy.
2. Concurrent arm - patients receive vinorelbine concurrently with fractions 1, 6, 15 and 20 of radical radiotherapy and cisplatin with fractions 1-4 and 16-19. Four weeks after concurrent treatment is completed patients receive 2 x 21 day cycle of vinorelbine and cisplatin.

Intervention Type

Mixed

Primary outcome(s)

Compare the overall survival of patients with stage III non-small cell cancer treated with chemotherapy comprising cisplatin and vinorelbine ditartrate (CV) followed by radical radiotherapy versus concurrent CV chemoradiotherapy followed by CV chemotherapy.

Key secondary outcome(s)

1. Compare the progression-free survival of patients treated with these regimens.
2. Compare the local progression-free survival (local control).
3. Compare the hematological, pulmonary, esophageal, and neurological toxicities.
4. Compare the response.
5. Compare the quality of life.
6. Compare the cost-effectiveness.

Completion date

30/04/2009

Eligibility

Key inclusion criteria

1. Histologically or cytologically confirmed stage III Non-Small Cell Lung Cancer (NSCLC)
2. Performance status - Eastern Cooperative Oncology Group (ECOG) zero or one
3. Life expectancy greater than three months
4. Tumour judged as inoperable by thoracic surgeon or after review by MultiDisciplinary Team (MDT) including thoracic surgeon, using British Thoracic Society guidelines
5. Age 18 or over
6. No prior chemotherapy, radiotherapy or investigational agents
7. Willing and able to give informed consent
8. Willing and able to complete quality of life forms
9. Patient considered able to tolerate platinum based chemotherapy and radical radiotherapy

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Stage IIIB disease with pleural effusion cytologically proven to be malignant
2. Superior vena cava obstruction
3. Other previous or current malignant disease likely to interfere with protocol treatment or comparisons

4. Abnormal Liver Function Tests (LFTs) with any of: Alkaline Phosphatase, Gamma Glutamyl Transferase, Transaminases or Bilirubin more than 1.5 times Upper Limit of Normal range (ULN)
5. Hypercalcaemia
6. Evidence of other significant laboratory finding or concurrent uncontrolled medical illness which in the opinion of the investigator would interfere with protocol treatment or results comparison or render the subject at high risk from treatment complications
7. Pregnancy and lactation. Effective contraception is mandatory for all patients (of reproductive potential) if sexually active
8. Active infection

Date of first enrolment

01/12/2005

Date of final enrolment

30/04/2009

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Clatterbridge Centre for Oncology

Liverpool

United Kingdom

CH63 4JY

Sponsor information

Organisation

Sponsor not defined - Record provided by CRUK and UCL CTC (UK)

Funder(s)

Funder type

Charity

Funder Name

Cancer Research UK (CRUK) (UK) (ref: C11922/A4558)

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 | 01/11/2014 | | Yes | No |
| Plain English results | | | | No | Yes |