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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.

Submission date 13/02/2004	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 10/03/2004	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 19/10/2018	**Condition category** Cancer	[_] 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

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Additional identifiers

EudraCT/CTIS number
2004-001920-19

IRAS number

ClinicalTrials.gov number
NCT00309972

Secondary identifying numbers
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 (NCSLC).

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

Secondary study design
Randomised controlled trial

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'

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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/12/2005

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
508

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
England

United Kingdom

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)

Sponsor details
Stephenson House
158-160 North Gower Street
London
United Kingdom
NW1 2ND

Sponsor type
Not defined

Funder(s)

Funder type
Charity

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

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	01/11/2014		Yes	No