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The Big Lung Trial: Does Short-Term Chemotherapy Improve the Survival of Patients with Non-Small Cell Lung Cancer (NSCLC)

Submission date 19/08/2002	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/08/2002	**Overall study status** Completed	
Last Edited 26/10/2018	**Condition category** Cancer	

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/blt-the-big-lung-trial2

Contact information

Type(s)
Scientific

Contact name
Dr - -

Contact details
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MRC Clinical Trials Unit
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United Kingdom
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
BLT

Study information

Scientific Title
The Big Lung Trial: Does Short-Term Chemotherapy Improve the Survival of Patients with Non-Small Cell Lung Cancer (NSCLC)

Study objectives
Not provided at time of registration

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Lung (non-small cell)

Interventions
1. CHEMOTHERAPY REGIMEN: Three cycles of one of the following regimens should be given: Cisplatin plus vindesine; Mitomycin C, ifosfamide and cisplatin; Mitomycin C, vinblastine and cisplatin; Navelbine and Cisplatin.

Chemotherapy may be given as follows:
A. Adjuvant Chemotherapy Option: Chemotherapy to start as soon as possible after surgery or following completion of radical radiotherapy.
B. Neo-adjuvant Option: Chemotherapy should start as soon as possible.
C. Supportive Care Group: Chemotherapy should start as soon as possible after randomisation and be given concurrently with supportive care.

2. CONTROL REGIMEN: No chemotherapy.

Intervention Type

Other

Phase
Not Specified

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/1995

Completion date
31/12/2005

Eligibility

Key inclusion criteria
1. Fulfil local criteria for diagnosis of NSCLC
2. Be fit to receive, and have no clear contraindications to chemotherapy
3. Patients randomised to adjuvant chemotherapy should be able to start chemotherapy within 10 weeks of completion of surgery or radical radiotherapy
4. No concurrent malignancy, or any history of malignancy, other than non-melanomatous skin cancer within the last 3 years

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/1995

Date of final enrolment
31/12/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
UKCCCR Register Co-ordinator
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
NHS R&D 'Time-Limited' National Programmes

Sponsor details
Commissioning Units
Canynge Hall
Whiteladies Road
Bristol
United Kingdom
BS8 2PR

Sponsor type
Government

ROR
https://ror.org/02wnqcb97

Funder(s)

Funder type
Government

Funder Name
NHS Research and Development Programme (UK)

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	01/07/2004		Yes	No
Results article	results	01/05/2005		Yes	No
Results article	results	20/10/2005		Yes	No