ISRCTN46536242 https://doi.org/10.1186/ISRCTN46536242

Post-Operative Radiotherapy for Non-Small Cell Lung Cancer

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 15/11/2019	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
LU11

Study information

Scientific Title
Post-Operative Radiotherapy for Non-Small Cell Lung Cancer

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) cancer

Interventions
Patients are randomised two to four weeks postoperatively to either:
1. Schedule R: Radiotherapy 40 Gy given in daily fractions five days a week over three weeks to mediastinum starting four to six weeks post-operatively.
2. Schedule NoR: No further specific treatment including post-operative radiotherapy unless or until the disease recurrence.

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
01/01/2002

Completion date
31/12/2002

Eligibility

Key inclusion criteria
1. Either sex, aged 75 years or less
2. World Health Organisation (WHO) performance status zero to two
3. Lung and cardiac function adequate for proposed resection
4. pT1 pN1 M0, pT2 pN1 M0, pT1 pN2 M0 or pT2 pN2 M0 non-small cell lung cancer
5. Complete resection of non-small cell lung cancer

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration.

Total final enrolment
308

Key exclusion criteria
1. Previous specific anti-cancer treatment for current disease
2. Presence of other malignant disease, except basal cell carcinoma or in situ carcinoma of the cervix
3. Presence of other serious condition contraindicating surgery or radiotherapy

Date of first enrolment
01/01/2002

Date of final enrolment
31/12/2002

Locations

Countries of recruitment
England

United Kingdom

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

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Sponsor details
20 Park Crescent
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+44 (0)20 7636 5422
clinical.trial@headoffice.mrc.ac.uk

Sponsor type
Research council

Website
http://www.mrc.ac.uk

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

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?
Results article	results	01/08/1996	15/11/2019	Yes	No