Post-Operative Radiotherapy for Non-Small Cell Lung Cancer

Submission date	Recruitment status	Prospectively registered		
19/08/2002	No longer recruiting	☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
19/08/2002	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
15/11/2019	Cancer			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr - -

Contact details

UKCCCR Register Co-ordinator MRC Clinical Trials Unit 222 Euston Road London United Kingdom NW1 2DA

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 London United Kingdom W1B 1AL +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

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