

A Phase III study of radical radiotherapy with or without gemcitabine in patients with T1-2 N0-1 M0 non-small cell lung cancer

Submission date 15/10/2002	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 15/10/2002	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 18/10/2018	Condition category Cancer	<input type="checkbox"/> Individual participant data

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
GRIN

Study information

Scientific Title

A Phase III study of radical radiotherapy with or without gemcitabine in patients with T1-2 N0-1 M0 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)

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

Lung (non-small cell) cancer

Interventions

Patients will be randomised to:

1. Radiotherapy (55 Gy 2.75 Gy 5 days/week over 4 weeks OR 60 Gy over 6 weeks with daily fractions of 2 Gy)
2. Gemcitabine (100 mg/m² IV over 30 min, 2-4 h prior to radiotherapy) plus radiotherapy

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Gemcitabine

Primary outcome measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/2003

Completion date

31/12/2005

Eligibility

Key inclusion criteria

1. Histological or cytological diagnosis of T1-2 N0-1 M0 NSCLC in patients deemed unfit for resection in the opinion of the thoracic surgeon
2. No prior chemotherapy or radiotherapy for the treatment of NSCLC
3. Performance status 0-2 on the Zubrod scale
4. Estimated life expectancy at least 12 weeks
5. <10% weight loss in the year preceding randomisation
6. Patient compliance and geographic proximity allowing adequate follow-up
7. Adequate bone marrow reserve
8. Adequate respiratory function
9. Radiologically measurable or non-measurable lesion
10. Aged at least 18 years
11. Written informed consent
12. Effective contraception (where appropriate) during and for at least 3 months following the trial

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Not provided at time of registration

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/01/2003

Date of final enrolment

31/12/2005

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

MRC Clinical Trials Unit

London

United Kingdom

NW1 2DA

Sponsor information

Organisation

University of Edinburgh (UK)

Sponsor details

The University of Edinburgh

Old College

South Bridge

Edinburgh

Scotland

United Kingdom

EH8 9YL

+44 (0)131 650 1000

communications.office@ed.ac.uk

Sponsor type

University/education

Website

<http://www.ed.ac.uk>

ROR

<https://ror.org/01nrxf90>

Funder(s)

Funder type

Industry

Funder Name

Educational grant from Lilly Oncology to University of Edinburgh (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	01/09/2012		Yes	No