

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	☒ Prospectively registered ☐ Protocol
Registration date 15/10/2002	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 18/10/2018	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr - -

Contact details

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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**

United Kingdom

England

Study participating centre

MRC Clinical Trials Unit

London

United Kingdom

NW1 2DA

Sponsor information

Organisation

University of Edinburgh (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

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	01/09/2012		Yes	No
Plain English results				No	Yes