ISRCTN61727489 https://doi.org/10.1186/ISRCTN61727489

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	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 15/10/2002	**Overall study status** Completed	
Last Edited 18/10/2018	**Condition category** 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
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 expectance 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/01nrxwf90

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