

Randomised trial of surgical resection with or without pre-operative chemotherapy in patients with operable non-small cell lung cancer (NSCLC) of any stage

Submission date 06/04/2000	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 06/04/2000	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 22/10/2018	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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00003159

Secondary identifying numbers

LU22

Study information

Scientific Title

Randomised trial of surgical resection with or without pre-operative chemotherapy in patients with operable non-small cell lung cancer (NSCLC) of any stage

Study objectives

To compare survival following surgical resection with or without pre-operative chemotherapy.

Secondary aims are to compare:

1. QL throughout the survival period; all items on the SF-36 questionnaire will be used to assess physical, emotional and functional health status, with particular emphasis on items that reflect the impact of symptoms on activities
2. Pre-randomisation clinical and post-surgery pathological staging
3. Resectability rates
4. Extent of surgery
5. Time to and site of relapse

And chemotherapy group, to document response evaluated according to the subjective investigators opinion following the WHO (1979) criteria, and clinician's assessment of the adverse effects of chemotherapy.

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

Health condition(s) or problem(s) studied

Non-small cell lung cancer (NSCLC)

Interventions

1. One group receives surgical resection with pre-operative chemotherapy.
2. The other group receives surgical resection alone.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Survival, quality of life, pre-randomisation clinical and post-surgery pathological staging, resectability rates, extent of surgery, time to and site of relapse

Secondary outcome measures

1. QL assessed before randomisation at 6 and 12 months from randomisation, and then annually, using the SF-36 questionnaire. All items and subscales will be examined according to the SF-36 manual. Analysis will be based on comparisons between regimens at the designated time points and on change from baseline for each regimen
2. Pre-randomisation clinical and post-surgery pathological staging
3. Resectability rates
4. Extent of surgery
5. Time to and site of relapse

Overall study start date

01/07/1997

Completion date

29/07/2004

Eligibility**Key inclusion criteria**

1. Previously untreated non small cell lung cancer
2. Tumour considered resectable
3. Either sex, any age
4. No evidence of distant metastases
5. Considered fit for chemotherapy and proposed surgical resection
6. WHO performance status 0, 1 or 2
7. No contraindication to chemotherapy or surgery
8. No other disease or previous malignancy likely to interfere with the protocol treatments
9. Patient willing and able to complete SF-36 questionnaires

Participant type(s)

Patient

Age group

Not Specified

Sex

Both

Target number of participants

600

Key exclusion criteria

Not provided at time of registration.

Date of first enrolment

01/07/1997

Date of final enrolment

29/07/2004

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Department of Oncology

Sutton

United Kingdom

SM2 5PT

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?
Plain English results				No	Yes
Results article	results	09/06/2007		Yes	No