

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

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 06/04/2000	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 22/10/2018	<b>Condition category</b> 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

**ClinicalTrials.gov (NCT)**  
NCT00003159

**Protocol serial number**  
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

## Study type(s)

Treatment

## 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(s)**

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

**Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Not Specified

**Sex**

All

**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

United Kingdom

England

### Study participating centre

Department of Oncology

Sutton

United Kingdom

SM2 5PT

## Sponsor information

### Organisation

Medical Research Council (MRC) (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, Medical Research Committee and Advisory Council, MRC

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### Location

United Kingdom

## 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?
<a href="#">Results article</a>	results	09/06/2007		Yes	No
<a href="#">Plain English results</a>				No	Yes