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# 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

**Registration date**
06/04/2000

**Overall study status**
Completed

**Last Edited**
22/10/2018

**Condition category**
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

### Primary study design
Interventional

### Study design
Randomised controlled trial

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