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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

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
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Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Sponsor details
20 Park Crescent
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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