

A randomised controlled dose intensification clinical trial of chemotherapy with or without recombinant human granulocyte colony stimulating factor (G-CSF) in small cell lung cancer (SCLC)

Submission date 13/03/2001	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 13/03/2001	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 19/09/2017	Condition category Cancer	☐ 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

Protocol serial number
LU19

Study information

Scientific Title

A randomised controlled dose intensification clinical trial of chemotherapy with or without recombinant human granulocyte colony stimulating factor (G-CSF) in small cell lung cancer (SCLC)

Study objectives

The aim of the trial is to investigate in patients with limited or extensive SCLC and good performance status, whether the addition of haemopoietic growth factor (G-CSF) to chemotherapy:

1. Improves survival
2. Permits shortening of the interval between cycles
3. Reduces toxic myelosuppression
4. Affects the quality of life during the first 6 months from randomisation

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)

Not Specified

Health condition(s) or problem(s) studied

Lung cancer

Interventions

The trial is designed to determine whether dose intensification with G-CSF is associated with a significant improvement in outcome compared with SCLC patients not receiving G-CSF. Patients with limited or extensive SCLC and a performance status of WHO 0-2 are randomised to receive ACE chemotherapy with or without G-CSF.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Haemopoietic growth factor (G-CSF)

Primary outcome(s)

Principle end-point is survival from randomisation

Key secondary outcome(s)

Secondary end-points are:

1. Interval between cycles of chemotherapy
2. Clinical septicaemic myelosuppression
3. WHO grade 3 or 4 neutropenia (less than 1000/mm³ cubed) 2 weeks after the first 3 cycles of chemotherapy
4. Quality of life
5. Days spent in hospital

Completion date

01/03/1996

Eligibility

Key inclusion criteria

1. Untreated, microscopically proven SCLC
2. World Health Organisation (WHO) performance status 0-2
3. Alkaline phosphatase (AP) and Alanine amino transferase (ALT) less than or equal to 2.5 x upper normal limit and serum creatine/urea less than or equal to 1.25 x upper normal limit
4. Not receiving any other investigational drugs
5. Female patients must not be pregnant

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/12/1993

Date of final enrolment

01/03/1996

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
MRC Clinical Trials Unit
London
United Kingdom
NW1 2DA

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

Date	Date	Peer	Patient-
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Output type Details		created	added	reviewed?	facing?
Results article	Cost effectiveness results	01/10/2006		Yes	No
Other publications	Analysis of messy longitudinal data from a randomized clinical trial. MRC Lung Cancer Working Party ()	15/10/2000		Yes	No