ISRCTN15921116 https://doi.org/10.1186/ISRCTN15921116

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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 13/03/2001	**Overall study status** Completed	
Last Edited 19/09/2017	**Condition category** Cancer	

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

Secondary identifying numbers
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 haemopoeitic 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.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

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)
Haemopoeitic growth factor (G-CSF)

Primary outcome measure
Principle end-point is survival from randomisation

Secondary outcome measures
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

Overall study start date
01/12/1993

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
400

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
England

United Kingdom

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

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Sponsor details
20 Park Crescent
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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?
Other publications	Analysis of messy longitudinal data from a randomized clinical trial. MRC Lung Cancer Working Party ()	15/10/2000		Yes	No
Results article	Cost effectiveness results	01/10/2006		Yes	No