ISRCTN36984145 https://doi.org/10.1186/ISRCTN36984145

Medical Research Council Sixth Small Cell Study: A Controlled Clinical Trial of Two Policies of Chemotherapy for Poor Prognosis Patients with Small-Cell Lung Cancer (SCLC)

Submission date
19/08/2002

Recruitment status
No longer recruiting

Registration date
19/08/2002

Overall study status
Completed

Last Edited
15/11/2019

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

Contact name
Dr - -

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

LU12

Study information

Scientific Title
Medical Research Council Sixth Small Cell Study: A Controlled Clinical Trial of Two Policies of Chemotherapy for Poor Prognosis Patients with Small-Cell Lung Cancer (SCLC)

Study objectives
(Added 05/08/09) What is the comparison in poor prognosis patients with SCLC with the standard chemotherapy used in 3 previous MRC studies, etoposide, cyclophosphamide, methotrexate and vincristine (ECMV) and 3 courses of etoposide & vincristine (EV), with respect to palliation of symptoms, performance status, toxicity, response to treatment and survival?

As of 05/08/09 this record has been extensively updated. All updates can be found under the relavent field with the above update date. Please also note that the trial start and end dates have been changed from 19/08/2002 and 19/08/2003 respectively, as these dates were automatically generated by the system at time of registration.

Ethics approval required
Old ethics approval format

Ethics approval(s)
No ethics information required 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
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Lung (small cell) cancer

Interventions
1. ECMV Regimen: Three courses three weeks apart of Etoposide, Cyclophosphamide, Methotrexate and Vincristine.

2. EV Regimen: Three courses three weeks apart of Etoposide and Vincristine. Thoracic radiotherapy and prophylactic cranial irradiation should not be given as a routine. If a patient needs radiotherapy to metastatic sites or to the primary site to control symptoms, the details should be decided by the radiotherapist and recorded as appropriate.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Etoposide, cylophosphamide, mathotrexate, vincristine

Primary outcome measure
Added 05/08/09:
1. Palliation of symptoms
2. Toxicity
3. Performance status
4. Quality of life
5. Response rate

Initial outcome measures not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/04/1997

Completion date
31/03/1999

Eligibility

Key inclusion criteria
1. Primarily untreated microscopically confirmed SCLC
2. Age <80
3. Limited disease: poor performance status (World Health Organisation [WHO] grade 3 or 4). Extensive disease: performance status any grade
4. Renal function normal
5. Plasma Billirubin not greater than twice normal levels

Participant type(s)
Patient

Age group
Not Specified

Sex

Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
1. Previous anticancer treatment for current SCLC
2. Presence of other malignant disease (except previous basal cell carcinoma or in situ carcinoma of the cervix)
3. Presence of other serious condition contraindicating the study regimens

Date of first enrolment
01/04/1997

Date of final enrolment
31/03/1999

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
UKCCCR Register Co-ordinator
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Sponsor details
20 Park Crescent
London
United Kingdom
W1B 1AL
+44 (0)20 7636 5422
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 Reseach Council (MRC) (UK)

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?
Results article	results	01/02/1996	15/11/2019	Yes	No