

A randomised study of oral versus intravenous chemotherapy in poor prognosis small cell lung cancer (SCLC)

Submission date 01/07/2001	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 01/07/2001	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 13/06/2014	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr - -

Contact details

UKCCCR Register Co-ordinator
MRC Clinical Trials Unit
222 Euston Road
London
United Kingdom
NW1 2DA

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

TR9SCLC

Study information

Scientific Title

Study objectives

Not provided at time of registration

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

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)

Interventions

1. Regimen A: Chemotherapy, oral etoposide repeated every 3 weeks for six courses.
2. Regimen B: Multi-drug chemotherapy, CAV (cyclophosphamide, adriamycin, vincristine) alternating every 3 weeks with PE (etoposide, cisplatin). A total of six courses, three with each drug combination.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/1997

Completion date

31/12/2000

Reason abandoned (if study stopped)

Objectives no longer viable

Eligibility

Key inclusion criteria

1. Histologically or cytologically proven SCLC
2. Patients with extensive disease and poor prognosis, i.e., Eastern Cooperative Oncology Group (ECOG) performance 2 or 3 or alkaline phosphatase >1.5 upper limit normal range
3. Patients 75 years and over, whatever stage of disease, deemed fit for randomisation
4. No previous malignancy, except non-melanomatous skin cancer in the preceding 3 years
5. No medical contraindications to treatment
6. Adequate renal function

Participant type(s)

Patient

Age group

Senior

Sex

Not Specified

Target number of participants

Not provided at time of registration

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/01/1997

Date of final enrolment

31/12/2000

Locations

Countries of recruitment

England

United Kingdom

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

Sponsor information

Organisation
UK Co-ordinating Committee for Cancer Research (UKCCCR)

Sponsor details
MRC Clinical Trials Unit
222 Euston Road
London
United Kingdom
NW1 2DA

Sponsor type
Government

ROR
<https://ror.org/054225q67>

Funder(s)

Funder type
Not defined

Funder Name
Not provided at time of registration

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	31/08/1996		Yes	No