ISRCTN73797340 https://doi.org/10.1186/ISRCTN73797340

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

Submission date 01/07/2001	**Recruitment status** Stopped	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data [_] Record updated in last year
Registration date 01/07/2001	**Overall study status** Stopped	
Last Edited 13/06/2014	**Condition category** Cancer	

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

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Not Specified

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(s)
Not provided at time of registration

Key secondary outcome(s)
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Senior

Sex
Not Specified

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
United Kingdom

England

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

Sponsor information

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

ROR
https://ror.org/054225q67

Funder(s)

Funder type
Not defined

Funder Name
Not provided at time of registration

Results and Publications

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