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
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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