

Randomised controlled clinical trial of oral etoposide versus intravenous multi-drug chemotherapy in the palliative treatment of patients with Small-Cell Lung Cancer (SCLC) and a poor prognosis

Submission date 19/08/2002	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 19/08/2002	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 15/11/2019	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
LU16

Study information

Scientific Title

Randomised controlled clinical trial of oral etoposide versus intravenous multi-drug chemotherapy in the palliative treatment of patients with Small-Cell Lung Cancer (SCLC) and a poor prognosis

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

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Small-Cell Lung Cancer (SCLC)

Interventions

1. Oral Etoposide Regimen (E): Four courses of oral etoposide twice daily for ten days at three week intervals (i.e. ten days of chemotherapy in each three week period).

2. Intravenous Multi-Drug

Chemotherapy Regimen (EV or CAV): Clinicians chose to use one of two multi-drug chemotherapy regimens: EV: Intravenous etoposide and vincristine four courses given at three week intervals, each course given over three days according to the protocol.

CAV: Intravenous cyclophosphamide, doxorubicin and vincristine four courses given at three week intervals, each course given on one day.

All treatments should start as soon as possible after randomisation.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Etoposide, cyclophosphamide, doxorubicin and vincristine

Primary outcome(s)

Not provided at time of registration.

Key secondary outcome(s)

Not provided at time of registration.

Completion date

01/08/2003

Eligibility

Key inclusion criteria

1. Microscopically proven SCLC
2. Limited or extensive disease
3. World Health Organisation (WHO) performance status grade two, three or four
4. No previous chemotherapy, radiotherapy, or surgery for small-cell lung cancer
5. No other previous or concomitant malignant disease, except basal cell carcinoma or in situ carcinoma of the cervix
6. No other serious condition contraindicating treatment with cytotoxic chemotherapy. Patients with evidence of liver cell damage are eligible
7. Renal function normal: plasma creatinine or urea concentration within normal limits
8. Plasma Billirubin less than 35 µmol/l
9. Any age, either sex

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Total final enrolment

339

Key exclusion criteria

Not provided at time of registration.

Date of first enrolment

01/08/2002

Date of final enrolment

01/08/2003

Locations

Countries of recruitment

United Kingdom

England

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

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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	15/11/2019	Yes	No