ISRCTN57675565 https://doi.org/10.1186/ISRCTN57675565

A randomised study of Mitomycin, Vinblastine and Platinum (cisplatin) (MVP) three versus six cycles in advanced Non-Small Cell Lung Cancer (NSCLC)

Submission date
19/08/2002

Recruitment status
No longer recruiting

Registration date
19/08/2002

Overall study status
Completed

Last Edited
16/04/2019

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
NCT00004209

Secondary identifying numbers
95.24

Study information

Scientific Title
A randomised study of Mitomycin, Vinblastine and Platinum (cisplatin) (MVP) three versus six cycles in advanced Non-Small Cell Lung Cancer (NSCLC)

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)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Interventions
Cisplatin 50 mg/m2 Mitomycin-C 8 mg/m^2 intravenous (iv) day one
Vinblastine 6 mg/m^2 iv day one

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Mitomycin, vinblastine and platinum (cisplatin)

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/1993

Completion date
30/11/1998

Eligibility

Key inclusion criteria
1. Histological evidence of NSCLC
2. Stage IIIb or IV disease not eligible for surgery or radical radiotherapy
3. Performance status zero, one or two
4. Ability to give signed, informed consent
5. 51Cr Ethylene Diamine Tetraacetic Acid (EDTA) more than 60 ml/min, creatinine clearance more than 60 ml/min, Haemoglobin (Hb) more than 10 g/dl, White Cell Count (WCC) more than 3 x 10^9/l, platelets 100 x 10^12/l, Liver Function Tests (LFTs) not more than two times normal unless due to metastatic disease

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

Total final enrolment
308

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/1993

Date of final enrolment
30/11/1998

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
MRC Clinical Trials Unit
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Cancer Research UK (CRUK) (UK)

Sponsor details
PO Box 123
Lincoln's Inn Fields
London
United Kingdom
WC2A 3PX
+44 (0)207 317 5186
kate.law@cancer.org.uk

Sponsor type
Charity

Website
http://www.cancer.org.uk

ROR
https://ror.org/054225q67

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

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	01/03/2001	16/04/2019	Yes	No