A Randomised Study of MVP (Mitomycin-C, Vinblastine and Moderate Dose Cisplatin) Three versus Six Cycles in Advanced Non-Small Cell Lung Cancer

Submission date 19/08/2002	Recruitment status No longer recruiting	 Prospectively registered Protocol
Registration date 19/08/2002	Overall study status Completed	 Statistical analysis plan Results
Last Edited 10/10/2012	Condition category Cancer	 Individual participant data Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

L14

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

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

Interventions

All patients receive chemotherapy with MVP (mitomycin-C, vinblastine and moderate dose cisplatin) repeated every 21 days for three courses. Mitomycin-C in given with the first and second course only.

Patients responding to treatment or with stable disease are randomised to either: 1. Arm A: Three further cycles of MVP chemotherapy. Mitomycin-C is given with the first and third course only.

2. Arm B: Best supportive care.

Intervention Type

Drug

Phase Not Specified

Drug/device/biological/vaccine name(s)

Mitomycin-C, Vinblastine and Moderate Dose Cisplatin

Primary outcome measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/2000

Completion date

31/12/2005

Eligibility

Key inclusion criteria

1. Histological evidence of non-small cell lung cancer

2. Stage IIIb or IV disease not eligible for neoadjuvant chemotherapy and/or radical radiotherapy

3. Performance status <2 (Zubrod-Eastern Cooperative Oncology Group [ECOG]-World Health Organisation [WHO] scale)

4. Adequate renal, bone marrow, and lung function tests unless due to metastatic disease

5. Patients must already have achieved symptom relief after three cycles of MVP chemotherapy

- 6. No uncontrolled infection
- 7. No previous conventional chemotherapy prior to MVP. One prior phase I/II new drug is allowed
- 8. No medical contraindications to treatment protocols

Participant type(s)

Patient

Age group Not Specified

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 01/01/2000

Date of final enrolment 31/12/2005

Locations

Countries of recruitment England

United Kingdom

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

Sponsor information

Organisation The Royal Marsden NHS Foundation Trust (UK)

Sponsor details Downs Road Sutton England United Kingdom SM2 5PT

Sponsor type Hospital/treatment centre

ROR https://ror.org/0008wzh48

Funder(s)

Funder type Hospital/treatment centre

Funder Name Royal Marsden Hospital (UK)

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