

Open, randomised phase III study assessing the toxicity and efficacy of platinum-based chemotherapy with vitamin supplementation in the treatment of lung cancer

Submission date 11/11/2005	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 24/11/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 03/03/2015	Condition category Cancer	☐ 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

Study information

Scientific Title

Open, randomised phase III study assessing the toxicity and efficacy of platinum-based chemotherapy with vitamin supplementation in the treatment of lung cancer

Acronym

MVPV1

Study objectives

To assess whether the addition of vitamin supplementation to chemotherapy may decrease treatment related toxicity and improve efficacy and outcome

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by the Royal Marsden Hospital, 20/01/2006, ref: 05/Q0801/178

Primary study design

Interventional

Study design

Open randomised phase III trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Lung cancer

Interventions

Cisplatin-based chemotherapy +/- vitamin supplementation

Intervention Type

Mixed

Primary outcome(s)

1. Incidence of neutropenia
2. Incidence of mucositis
3. Incidence of emesis

Key secondary outcome(s)

1. Disease response by Response Evaluation Criteria in Solid Tumors (RECIST) criteria
2. Response rate
3. Overall survival

Completion date

01/01/2008

Eligibility

Key inclusion criteria

1. Written informed consent
2. Male or female, aged over 18 years
3. Histologically or cytologically confirmed Non-Small Cell Lung Cancer (NSCLC), SCLC or mesothelioma: locally advanced or metastatic; where giving cisplatin 75 mg/m² is appropriate

4. Eastern Cooperative Oncology Group (ECOG): performance status (PS) zero to two
5. Lab requirements at entry: serum creatinine less than or equal to 1.25 Upper Limit of Normal (ULN), creatinine clearance more than 50 ml/min (Ethylene Diamine Tetra-acetic Acid [EDTA]) or more than 60 ml/min (C+G), white blood cell count (WBC) more than $3 \times 10^9/l$, neutrophils more than $1.5 \times 10^9/l$, platelets more than $100 \times 10^9/l$
6. Presence of at least one bi-dimensionally measurable index lesion
7. Effective contraception if indicated
8. Estimated life expectancy of at least 12 weeks
9. Patients are required to stop all complimentary medicines and prior vitamin supplements

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Pregnant or lactating women
2. Active infection
3. Inability or unwillingness to take vitamin supplementation
4. Serious systemic disorders incompatible with the study at the discretion of the investigator

Date of first enrolment

01/01/2006

Date of final enrolment

01/01/2008

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Royal Marsden Hospital

Sutton

United Kingdom

SM2 5PT

Sponsor information

Organisation

Royal Marsden Hospital (UK)

ROR

<https://ror.org/034vb5t35>

Funder(s)

Funder type

Government

Funder Name

Royal Marsden NHS Foundation Trust

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	11/12/2014		Yes	No