Modafinil for the treatment of fatigue in lung cancer: a pilot study

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
12/04/2006		☐ Protocol		
Registration date 24/04/2006	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	Individual participant data		
26/10/2022	Cancer			

Plain English summary of protocol

https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-treatment-for-extreme-tiredness-and-exhaustion-in-people-with-advanced-lung-cancer

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Modafinil for the treatment of fatigue in lung cancer: a pilot study

Study objectives

To determine the feasibility of conducting a future randomised controlled trial investigating the use of modafinil in cancer-related fatigue (by generating data to allow a sample size calculation, establishing recruitment and attrition rates, determining whether appropriate outcomes measures and assessment intervals have been chosen, and generating limited tolerability data of modafinil in patients with cancer)

Ethics approval required

Old ethics approval format

Ethics approval(s)

South East Multicentre Research Ethics Committee on 06/07/2005, (ref: 05/MRE01/60)

Study design

Interventional, open-label, uncontrolled pilot study

Primary study design

Interventional

Secondary study design

Non randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Quality of life

Participant information sheet

Health condition(s) or problem(s) studied

Non small cell lung cancer

Interventions

Modafinil 100 mg daily for one week, increasing to 200 mg daily for one week

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Modafinil

Primary outcome measure

Change in fatigue

Secondary outcome measures

Change in sleepiness and depression levels

Overall study start date

26/04/2006

Completion date

18/05/2007

Eligibility

Key inclusion criteria

- 1. Histologically or cytologically confirmed non-small cell lung cancer (NSCLC)
- 2. A fatigue score of four using bimodal scoring in the Chalder fatigue scale
- 3. World Health Organisation (WHO) performance status of 0-3
- 4. Ability to give informed consent to participate

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

20

Total final enrolment

208

Kev exclusion criteria

- 1. Received radiotherapy or chemotherapy within the last four weeks
- 2. Commenced on antidepressants or steroids (corticosteroids and progestational steroids) within the last two weeks
- 3. Received blood transfusion within the last two weeks
- 4. Potentially fertile women of child-bearing age
- 5. Uncontrolled moderate to severe hypertension, arrhythmia
- 6. Previous adverse reaction to modafinil or other central nervous system (CNS) stimulant
- 7. Current active involvement in another clinical trial

Date of first enrolment

26/04/2006

Date of final enrolment

18/05/2007

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Palliative Care Office
Cambridge
United Kingdom
CB2 2QQ

Sponsor information

Organisation

Cambridge University Hospitals NHS Foundation Trust (UK)

Sponsor details

Research and Development Department Box 146 Addenbrookes Hospital Cambridge England United Kingdom CB2 2QQ

Sponsor type

University/education

ROR

https://ror.org/04v54gi93

Funder(s)

Funder type

Government

Funder Name

Internal funding from Addenbrookes Hospital, Cambridge, UK and from Peterborough District Hospital Peterborough (UK)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

Not provided at time of registration

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	01/06/2009		Yes	No
Plain English results			26/10/2022	No	Yes