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

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

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Additional identifiers

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)

Primary study design
Interventional

Study design
Interventional, open-label, uncontrolled pilot study

Study type(s)
Quality of life

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(s)
Change in fatigue

Key secondary outcome(s)
Change in sleepiness and depression levels

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

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Total final enrolment
208

Key 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
United Kingdom

England

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

Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust (UK)

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type
Government

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

Results and Publications

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