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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

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

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
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/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

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