ISRCTN34021674 https://doi.org/10.1186/ISRCTN34021674

A randomised, placebo-controlled, rising dose, crossover study to evaluate the effectiveness of modafinil in the management of fatigue in fibromyalgia

Submission date
04/08/2005

Recruitment status
Stopped

Registration date
10/10/2005

Overall study status
Stopped

Last Edited
18/03/2010

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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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Additional identifiers

Protocol serial number
REC 7197

Study information

Scientific Title

Acronym
M & F

Study objectives
That patients receiving modafinil will report less subjective fatigue, reduced sleepiness, improved physical health and vitality scores on the SF36 and will demonstrate improved psychomotor and cognitive skills, compared with those receiving placebo.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised placebo-controlled rising dose crossover study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Fibromyalgia

Interventions
TRIAL TERMINATED 02 MARCH 2006 BEFORE ANY RECRUITMENT OF PATIENTS.
The modafinil group (Gp 2) will take one 100 mg modafinil tablet each morning on days 1-7, increasing to 200 mg on days 8-14 and 300 mg on days 15-35. The placebo group (Gp 1) will take placebo tablets according to the same regime. After a one week washout period, Gp 1 will take modafinil and Gp 2, placebo, repeating the rising-dose schedule.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Modafinil

Primary outcome(s)
To determine whether modafinil is more effective than placebo in reducing subjective fatigue as measured by the Brief Fatigue Inventory.

Key secondary outcome(s)

1. Memory, attention and psychomotor speed
2. Daytime sleepiness as measured by the Epworth Sleepiness Scale
3. Subjective measures of sleep quality and disturbance
4. Sleep duration as measured by actigraphy
5. Subjective measures of sleep duration, as reported in sleep diaries
6. Subjective measures of physical vitality, psychological and social function as assessed by the short-form health survey, SF36
7. Pain, as measured by the Short-form McGill Pain Questionnaire (SF-MPQ)

Completion date
01/12/2006

Reason abandoned (if study stopped)
Objectives no longer viable

Eligibility

Key inclusion criteria
1. Aged between 18 and 65 years inclusive, male or female of any ethnic origin and fluent in English
2. Widespread body pain - defined as pain on both sides of the body, and above and below the waist. Pain must be present in the axial skeleton, or anterior chest or thoracic spine or low back.
3. A positive tender point count defined as at least 11 out of 18 tender points on digital palpation of approximately 4 kg
4. Daily fatigue of greater than 4 points as assessed by the 14-item Fatigue Scale
5. Patient reports fatigue for >24 hours after minimal activity
6. Patient is willing and able to participate in computer-based testing and to maintain a sleep diary for the duration of the study
7. Written, informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

Key exclusion criteria

1. Major psychological disorders known to affect sleep, as assessed by the Primary Care Evaluation of Mental Disorders'
2. Any other sleep disorder including obstructive sleep apnoea, narcolepsy or periodic leg movement syndrome
3. A history of inflammatory disease or neoplasm
4. Pregnancy or lactation
5. Hypertension at a level that in the clinicians opinion precludes the patient from participation in the study
6. A score of ≤23 on the Mini-Mental State Exam

7. Previous use of modafinil
8. A clinical history of heart, kidney or liver disease, heart attack, diseases of the central nervous system (CNS), alcoholism or drug dependence
9. Use of benzodiazepines, lithium or antipsychotic drugs

Date of first enrolment
01/09/2005

Date of final enrolment
01/12/2006

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Consultant Anaesthetist
Leicester
United Kingdom
LE5 4PW

Sponsor information

Organisation
University Hospitals of Leicester NHS Trust (UK)

ROR
https://ror.org/02fha3693

Funder(s)

Funder type
Industry

Funder Name
Cephalon UK Independent Research Programme grant (UK).

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration