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Double-blind randomised controlled cross-over trial to determine the effect of low dose melatonin on sleep disorders in the elderly

Submission date
23/01/2004

Recruitment status
No longer recruiting

Registration date
23/01/2004

Overall study status
Completed

Last Edited
11/01/2010

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RDC00970

Study information

Scientific Title

Study objectives
There has recently been a considerable growth of interest in the therapeutic potential of the pineal hormone melatonin. Exogenous low-dose melatonin has been shown to be a safe and effective treatment of conditions where there is a disturbance of the sleep-wake cycle. In elderly subjects without mental illness, melatonin is effective in treating sleep disturbance.
Disruption of sleep is especially common with reversal of the sleep-wake cycle. Not only does disruption of the sleep pattern cause considerable distress to patients, it is also one of the major problems encountered by carers. Indeed, a breakdown of care by relatives has significant economic implications. Since dementia is also associated with disturbance of circadian rhythm and exogenous melatonin is effective in entraining the sleep cycle in normal subjects, we propose a trial to test the hypothesis that exogenous low dose melatonin will improve sleep in elderly subjects with dementia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised placebo controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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

Interventions
1. Low dose melatonin
2. Placebo

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. An improvement in patents sleep quality and duration with melatonin compared with placebo.
2. An improvement in carers quality of life because if less disruption by restless patients.
3. A decrease in need for other more potent medications with significant side effects.
The main outcome measure used will be improvement in length of sleep and a decrease in periods of nocturnal wakening for the periods 10 pm and 8 am.
Objective measures will be made using a validated sleep activity and pulse logger (Somnitor) (Cole et al 1992).
Subsidiary outcome measures will include: recordings of sleep using a sleep diary ratings on quality of sleep using Visual Analogue Scales, carer rating scales and the use of prescribed hypnotic
medication.

Secondary outcome measures
Not provided at time of registration

Overall study start date
03/08/1998

Completion date
03/09/2000

Eligibility

Key inclusion criteria
1. Patients aged over 65 years. Either gender.
2. Clinical Diagnostic Statistical Manual, IV edition (DSM-IV). Axix I diagnosis of dementia of Alzheimer's type.
3. Inpatients or patients living at home and managed by carers.

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
Not provided at time of registration

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment

03/08/1998

Date of final enrolment
03/09/2000

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Free Hospital School of Medicine
London
United Kingdom
NW3 2PF

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details
The Department of Health
Richmond House
79 Whitehall
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United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
NHS Executive London (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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	01/12/2002		Yes	No