

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	<input type="checkbox"/> Prospectively registered
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 11/01/2010	Condition category Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

Protocol serial number
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

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Dementia

Interventions

1. Low dose melatonin
2. Placebo

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

1. An improvement in patients sleep quality and duration with melatonin compared with placebo.
2. An improvement in carers quality of life because of 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 waking 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.

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Senior

Sex

All

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

United Kingdom

England

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)

Funder(s)

Funder type

Government

Funder Name

NHS Executive London (UK)

Results and Publications

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