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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	Recruitment status	[ ] Prospectively registered
23/01/2004	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
23/01/2004	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
11/01/2010	Nervous System Diseases	

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 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.

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