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Efficacy of prolonged-release melatonin versus placebo in a three-week treatment of diabetic patients suffering from insomnia

Submission date	Recruitment status	[ ] Prospectively registered
25/02/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
27/02/2009	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
27/02/2009	Nervous System Diseases	[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Neu951005

Study information

Scientific Title
A randomised double-blind, crossover study comparing the efficacy of prolonged-release melatonin versus placebo in a three-week treatment of diabetic patients suffering from insomnia

Study objectives
Type 2 uncontrolled diabetic patients often have low endogenous melatonin and suffer from sleep disorders. The effect of a prolonged-release melatonin (PRM) formulation on glucose lipid metabolism and sleep is studied in type 2 diabetes patients with insomnia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the E. Wolfson Medical Centre Holon, approved on 01/11/1995 (ref: 5471)

Study design
Randomised double-blind placebo-controlled crossover trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Type 2 diabetes mellitus, insomnia

Interventions
In a randomised, double-blind, crossover study, the subjects were treated for 3 weeks with 1 tablet per night of 2 mg prolonged-release melatonin (Circadin®) (oral) or placebo, with one week washout period in between.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

Sleep efficiency (Time Frame: 3 weeks). Efficacy of sleep quality was objectively monitored by a wrist actigraphy device (Somnitor™). Sleep efficiency is the percentage of time patients were asleep while in bed as scored by the actigraphic sleep algorithm.

Secondary outcome measures
Safety. Total duration of follow-up: 3 weeks

Overall study start date
01/11/1995

Completion date
01/03/1997

Eligibility

Key inclusion criteria
Independently living male and female patients (no age limits) who complained of insomnia and suffer from diabetes.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
36

Key exclusion criteria
Patients with liver or renal problems (serum creatinine above 1.5 mg/dL).

Date of first enrolment
01/11/1995

Date of final enrolment
01/03/1997

Locations

Countries of recruitment
Israel

Study participating centre

Neurim Pharmaceuticals Ltd.
Tel Aviv
Israel
69710

Sponsor information

Organisation
Neurim Pharmaceuticals Ltd. (Israel)

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Sponsor type
Industry

Website
http://www.neurim.com

ROR
https://ror.org/01gd1jq14

Funder(s)

Funder type
Industry

Funder Name
Neurim Pharmaceuticals Ltd. (Isreal)

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