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

Contact name

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Contact details

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Additional identifiers

Protocol serial number 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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s))

Safety. Total duration of follow-up: 3 weeks

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

ROR

https://ror.org/01gd1jq14

Funder(s)

Funder type

Industry

Funder Name

Neurim Pharmaceuticals Ltd. (Isreal)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration