

Melatonin in doctors and nurses working nightshifts

Submission date 19/02/2016	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 22/02/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 12/08/2022	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Melatonin is a hormone produced by the brain that controls sleeping patterns. Levels peak at around 4am, and when night shift workers attempt to sleep in the daytime when melatonin levels are low, a 'mismatch' between melatonin levels and timing of sleep occurs. It takes several days to adapt. A 'transcriptome' is a collection of RNA molecules produced by a particular cell or tissue. The transcriptome can vary with the external environment, and changes in the transcriptome can tell us a lot about gene activity. Recent studies have shown that when there is a mismatch between melatonin production and sleep patterns, there are changes in the transcriptome. Night shift working has been associated with adverse health effects, which might be related to transcriptome changes. Poorer performance and alertness has been reported in night shift workers and this continues until the timing of melatonin production has changed to match sleeping patterns. Administration of melatonin has been used previously in 'jet lag', which is a similar situation to that of night shift workers. However, it is unknown whether taking a dose of melatonin affects transcriptome changes or if it helps sleeping patterns and work performance to recover quicker. Melatonin has an excellent safety profile and may be used as a new treatment to improve sleep patterns, improve performance and possibly correct the adverse health effects of night shift working. The aim of this study is to determine the effects of giving doses of melatonin in medical staff working night shifts, and to assess whether melatonin given before sleep time is able to improve sleep, improve alertness and affect transcriptome changes.

Who can participate?

Doctor and nurses working two series of night shifts at least 4 weeks apart

What does the study involve?

Each participant is studied twice - during one series of night shifts they take melatonin and during the other series of night shifts they take a placebo (dummy drug). The order in which they take melatonin or placebo is decided randomly. They complete questionnaires about their normal sleeping habits, their sleeping patterns during the night shift and how sleepy they feel. Participants' alertness is assessed using a computer reaction test and blood samples are taken to measure transcriptome changes. Participants also wear a wristband monitor during sleep periods to obtain data on their sleeping patterns and restlessness.

What are the possible benefits and risks of participating?

The study will tell us whether melatonin might help people undertaking night shifts adapt more quickly to a new sleeping pattern and whether taking melatonin affects the transcriptome changes which have been previously described, which may improve adverse health outcomes.

Where is the study run from?

University of Aberdeen/NHS Grampian (UK)

When is the study starting and how long is it expected to run for?

April 2016 to March 2018

Who is funding the study?

Chief Scientist Office

Who is the main contact?

Prof Helen Galley

Contact information

Type(s)

Scientific

Contact name

Prof Helen Galley

ORCID ID

<https://orcid.org/0000-0002-9517-0074>

Contact details

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Additional identifiers

Clinical Trials Information System (CTIS)

2015-004106-42

Protocol serial number

3-047-15

Study information

Scientific Title

Melatonin In Doctors and nurses working NIGHTshifts (MIDNIGHT): a randomised double-blind placebo-controlled crossover pilot study

Acronym

MIDNIGHT

Study objectives

The aim of this pilot study is to determine the effects of exogenous melatonin administration compared with placebo in medical staff working night shifts on the intensive care unit.

Ethics approval required

Old ethics approval format

Ethics approval(s)

North of Scotland research ethics committee 2, 17/02/2016

Study design

Randomised double-blind placebo-controlled crossover pilot study

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Doctors and nurses working nightshifts

Interventions

Subjects will take 6mg Circadin (slow release melatonin) or a matching placebo on three consecutive days during night shift working on two separate series of night shifts at least 4 weeks apart.

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

Circadin (melatonin)

Primary outcome(s)

The primary endpoint is successful completion of the trial, defined as recruitment, randomisation and protocol completion of 25 individuals i.e., both arms of the crossover design.

Key secondary outcome(s)

1. Determination of drop out, non completion and retention rate (end of trial)
2. Differential gene expression (blood samples on Day 1 before shift, and end of shifts series on Day 4)
3. Differential gene expression between placebo and active arms (blood samples Day 4 after each shift series)
4. Serum interleukin-6 and tumour necrosis factor alpha levels (blood samples on Day 1, and end

of shifts series on Day 4)

5. Serum IL-6 and TNFalpha levels after placebo and active arms (blood samples Day 4 after each shift series)

6. Serum melatonin and 6-hydroxymelatonin sulphate levels at each time point (blood samples on Day 1 before shift, and end of each shift for shift series)

7. Verran and Snyder-Halpern sleep scale, Epworth sleepiness scale, data from wristband activity monitor (VSH before each shift, ESS before, during and after each shift. Activity monitoring during each sleep period)

8. Psychomotor vigilance task, double digit addition test (PVT and DDAT before and after each shift)

9. Usual sleep habits and owl-lark questionnaires (before randomisation)

10. Questionnaire about trial (trial end)

11. Focus group about trial (trial end - requires additional consent)

Completion date

30/03/2018

Eligibility

Key inclusion criteria

1. Either sex
2. Non-smokers
3. Not taking regular medicine
4. No health complaints
5. Doctor or nurse working two series of night shifts at least 4 weeks apart

Participant type(s)

Health professional

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

25

Key exclusion criteria

1. Pregnant or trying to get pregnant
2. Breastfeeding
3. Use of sedatives, hypnotics, herbal remedies, sleeping pills
4. Taking medication except oral contraceptives

Date of first enrolment

01/04/2016

Date of final enrolment

30/08/2017

Locations**Countries of recruitment**

United Kingdom

Scotland

Study participating centre

University of Aberdeen/NHS Grampian

Research Governance Office

Foresterhill House Annexe

Foresterhill

Aberdeen

United Kingdom

AB25 2ZB

Sponsor information**Organisation**

University of Aberdeen/NHS Grampian (UK)

ROR

<https://ror.org/016476m91>

Funder(s)**Funder type**

Government

Funder Name

Chief Scientist Office

Alternative Name(s)

CSO

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	27/08/2020	17/11/2020	Yes	No
Basic results		12/03/2019		No	No
Protocol file	version 4.0	16/06/2016	12/08/2022	No	No