Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Study of the effects of short-term melatonin on salivary cortisol and sleep quality of hemodialysis patients

Protocol summary

Study aim
Determination of Short-term Effects of Melatonin on Salivary Cortisol Level and Sleep Quality in Hemodialysis Patients

Design
Clinical trial with control group, with parallel groups, double blind, randomized, with statistical software, with a sample size of 40 participants

Settings and conduct
This study is performed on patients with severe renal failure who are referred to Hemodialysis Center of Gorgan 5 Azar Hospital for dialysis. Of the eligible individuals with a score of 5 or more in the Pittsburgh Questionnaire, 40 patients are selected after numbering from 1 to 40. Saliva samples are taken from patients for measuring cortisol salivary at 11 o'clock before dialysis and at 8 o'clock in the morning before starting dialysis. Then, according to the data given by the software program, patients are in the two groups receiving the drug or placebo. Neither the research subjects nor the investigator have any information on the acceptability of each drug or placebo group. One group received 3 mg melatonin and another one received placebo for 2 weeks. At the end of 2 weeks, sampling is done to determine the salivary concentrations of cortisol. The Pittsburgh questionnaire is also filled up by participants for the purpose of assessing the quality of sleep

Participants/Inclusion and exclusion criteria
Inclusion Criteria : ESRD patients who have undergone hemodialysis for more than 3 months , Under-75 years old, More than 5 scores in the Pittsburgh questionnaire; Exclusion criteria : Seriuos and severe illness (malignancy, congestive heart failure and Active infection), pregnancy, iron deficiency anemia, uncontrolled diabetes mellitus (HbA1c> 7.5), severe depression, psychotic disorders, continuous use of medications that affect sleep, corticosteroid use

Intervention groups
In this study, one group received melatonin and another received placebo

Main outcome variables
Determination of short-term effects of melatonin on salivary cortisol level and overall sleep score in dialysis patients; Determine the relationship between cortisol salivary levels and overall sleep score before and after intervention

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180117038418N1**
Registration date: **2018-02-11, 1396/11/22**
Registration timing: **retrospective**

Last update: **2018-02-11, 1396/11/22**
Update count: **0**

Registration date
2018-02-11, 1396/11/22

Registrant information

Name
Elham Hasannia

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 17 3222 0563

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hasannia@goums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-01-21, 1396/11/01

Expected recruitment end date

2018-02-04, 1396/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effects of short-term melatonin on salivary cortisol and sleep quality of hemodialysis patients

Public title

Effect of melatonin on cortisol and sleep quality of Hemodialysis Patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

ESRD patients undergoing hemodialysis >3 months age <75 years Pittsburgh questionnare score >=5

Exclusion criteria:

serious and sever illness (e.g; malignancy, CHF, active infection) pregnancy iron deficiency anemia poor control diabet (HbA1c>7.5) sever deppresion psychotic disorders use of hypnotics continuelly use of corticosteroid

Age

To **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Individuals are randomly assigned to one study group with statistical software and receive intervention from the same group

Blinding (investigator's opinion)

Double blinded

Blinding description

Neither the research subjects nor the investigator have any information on the acceptability of each drug or placebo group

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of golestan University of Medical Sciences

Street address

Falsafi educational campus, Vice Chancellor of Technology and Information, 4 Kilometer of Gorgan-sari Road, Gorgan

City

gorgan

Province

Golestan

Postal code

4918936316

Approval date

2018-01-17, 1396/10/27

Ethics committee reference number

IR.GOUMS.REC.1396.246

Health conditions studied

1

Description of health condition studied

sleep disorder

ICD-10 code

G47

ICD-10 code description

Sleep disorders

2

Description of health condition studied

chronic renal failure

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

Primary outcomes

1

Description

Sleep quality score in Pittsburgh questionnaire

Timepoint

Sleep quality study at the beginning of the study (before the intervention) and 2 weeks later (end of study)

Method of measurement

Pittsburgh questionnaire

2

Description

Salivary Cortisol Level

Timepoint

Measurement of salivary cortisol level at the beginning of the study at night before and the next morning before

the start of dialysis and 2 weeks later (end of study) in the same way

Method of measurement

Cortisol measurement kit, chemiluminescence method

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 3 mg melatonin capsule made in Canada, which is consumed by participants for 2 weeks each night at 10 o'clock.

Category

Treatment - Drugs

2

Description

Control group: Chickpea flour capsules, which are consumed by participants for 2 weeks each night at 10 o'clock

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

5th Azar hospital in Gorgan

Full name of responsible person

Elham Hasannia

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Gorgan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Elham Hasannia

Position

Assistant

Latest degree

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available