

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effects of melatonin supplementation on parathyroid hormone levels in hemodialysis patients : A clinical trial study

Protocol summary

Study aim

To investigate the effect of oral melatonin supplementation on serum levels of PTH, vitamin D, calcium, phosphorus, magnesium, and other electrolytes in patients undergoing hemodialysis with secondary hyperparathyroidism.

Design

A two-group, parallel-group, double-blind (analyzer-blind), randomized, alternating-block, early clinical phase clinical trial on 88 hemodialysis patients. Group allocation was performed using sealed, coded envelopes by an outsider, and the sample size was determined to be 44 in each group.

Settings and conduct

Hemodialysis patients were selected based on the inclusion criteria and after informed consent, they were randomly divided into two groups. One group received oral melatonin 3 mg daily for 12 weeks and the control group received no pharmacological intervention. Serum levels of PTH, vitamin D, calcium, phosphorus, magnesium and other electrolytes were measured before and after the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 18 years, hemodialysis patients who have been on dialysis for at least three months, PTH hormone level above 300 Inclusion criteria: Presence of any active or chronic infection

Intervention groups

Hemodialysis patients who receive 3 mg of melatonin tablets per day, one hour before bedtime, for 12 weeks, and hemodialysis patients who do not receive any pharmacological intervention (melatonin) and only receive routine dialysis care, are in fact one group receiving melatonin and one group without pharmacological intervention (control).

Main outcome variables

Serum levels of PTH (parathyroid hormone), serum levels of vitamin D, serum levels of calcium, serum levels of phosphorus, serum levels of magnesium, serum levels of

other electrolytes. These variables will be measured before the start of the study and after 12 weeks of intervention in both groups and their changes will be examined.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251127068128N1**

Registration date: **2025-11-30, 1404/09/09**

Registration timing: **registered_while_recruiting**

Last update: **2025-11-30, 1404/09/09**

Update count: **0**

Registration date

2025-11-30, 1404/09/09

Registrant information

Name

Shahla Ahmadi Halili

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 916 681 6124

Email address

ahmadihalili-sh@ajums.ac.ir

Recruitment status

recruiting

Funding source

Expected recruitment start date

2025-11-15, 1404/08/24

Expected recruitment end date

2027-02-13, 1405/11/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of melatonin supplementation on parathyroid hormone levels in hemodialysis patients : A clinical trial study

Public title

The effect of melatonin consumption on parathyroid hormone levels in patients undergoing hemodialysis.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Over 18 years old Hemodialysis patients who have been on dialysis for at least three months PTH hormone level above 300 The presence of any active or chronic infection

Exclusion criteria:**Age**

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **88**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is prepared by a statistician. The intervention used in this study is assigned according to a randomization list by a person outside the study who is unaware of the research objectives and according to the corresponding codes in sealed envelopes. The patient and the doctor have no knowledge of how they are placed in the groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients and physicians do not know who is receiving melatonin, and the data analyst is not aware of the grouping. Group assignment is done by block randomization and coded envelopes by someone outside the study.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Jundishapur University of Medical Sciences, Koi Golestan, Ahvaz

City

Ahvaz

Province

Khuzestan

Postal code

6193673166

Approval date

2025-11-15, 1404/08/24

Ethics committee reference number

IR.AJUMS.REC.1404.465

Health conditions studied**1****Description of health condition studied**

Name of the disease and condition studied: Chronic kidney disease in hemodialysis patients with secondary hyperparathyroidism

ICD-10 code

N18

ICD-10 code description

Chronic kidney disease (CKD)

Primary outcomes**1****Description**

Serum PTH (parathyroid hormone) levels

Timepoint

Beginning of the study (before starting melatonin) End of week 12 (after 3 months of intervention)

Method of measurement

Measurement with standard laboratory kits from Imam Hospital

2**Description**

Serum vitamin D levels

Timepoint

Beginning of the study and end of week 12

Method of measurement

Venous blood sample, serum level determination with standard laboratory kit

3

Description

Serum levels of calcium, phosphorus, and magnesium

Timepoint

Beginning of the study and end of week 12

Method of measurement

Venous blood sample with standard laboratory kits

4

Description

Serum levels of other electrolytes

Timepoint

Beginning of the study and end of week 12

Method of measurement

Venous blood sample measurement with laboratory kits

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: Hemodialysis patients who received 3 mg of melatonin tablets per day, one hour before bedtime, for 12 weeks.

Category

Treatment - Other

2

Description

Control group: Hemodialysis patients who do not receive any pharmacological intervention (melatonin) and only receive routine dialysis care.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Golestan Hospital

Full name of responsible person

Shahla Ahmadi Halili

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Golestan Hospital, Koi Golestan, Ahvaz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Abdollah Rafiei

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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Shahla Ahmadi Halili

Position

Assistant Professor of Nephrology

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Latest degree

Subspecialist

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Latest degree

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Other areas of specialty/work

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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