

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jul 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)

##### Phone

+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**

Khouzestan

**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

##### **Street address**

Golestan Hospital, Koi Golestan, Ahvaz

##### **City**

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##### **Postal code**

3311761357

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##### **Email**

ahmadihalili-sh@ajums.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Ahvaz University of Medical Sciences

##### **Full name of responsible person**

Abdollah Rafiei

##### **Street address**

24 metery street, East sahely highway, Ahvaz

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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

##### **Street address**

Azadegan St., 24 meters from Imam Khomeini Hospital

##### **City**

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##### **Province**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Ahvaz University of Medical Sciences  
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**Position**  
Assistant Professor of Nephrology  
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## Person responsible for updating data

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**Name of organization / entity**  
Ahvaz University of Medical Sciences  
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Assistant Professor of Nephrology  
**Latest degree**  
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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