

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Evaluation of melatonin effects on oxidative stress in hemodialysied patient, A prospective, randomized, double-blind, controlled trial

Protocol summary

Study aim

Prevention and treatment of oxidative stress in patients undergoing dialysis

Design

Clinical trial has a group control, double blind, randomized, with 32 sample of phase 3 clinical trials.

Settings and conduct

In this study, the aim of community patients undergoing dialysis in dialysis section, referring to Taleghani hospital dialysis subjects under the direction of Urmia were enrolled in the study, a questionnaire that includes demographic information (age and sex), the history of the disease, history of drug use and smoking, were completed. Of the company's eligible applicants were fitted to request informed consent was prepared and signed study. Patients to assess blood samples were taken from biochemistry and the size of the testing decisions related to glutathione, catalase and SOD. Patients in the intervention group melatonin with 3 mg per day for 2 month. Patients in the control group as well as the placebo without markup, with colors, shapes, sizes, fitted, smell and taste the same in the same dose with melatonin was given the same term.

Participants/Inclusion and exclusion criteria

The terms of entry into the study. patients should be at least two months before the start of the study under dialysis. The terms of the withdrawal from the study patients. The patient throughout the surgery study

Intervention groups

The patients in the intervention group get melatonin with 3mg per day for 2 month. Patients in the control group as well as the placebo without markup, with colors, shapes, sizes, fitted, smell and taste the same in the same dose with melatonin was given the same term.

Main outcome variables

In this randomized, placebo controlled, melatonin levels of glutathione, catalase and SOD of chronic renal patients serum under dialysis significantly increases.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190120042430N1**

Registration date: **2019-03-11, 1397/12/20**

Registration timing: **retrospective**

Last update: **2019-03-11, 1397/12/20**

Update count: **0**

Registration date

2019-03-11, 1397/12/20

Registrant information

Name

zahra rezai

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3672 8966

Email address

d.z73rezai@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-11-22, 1396/09/01

Expected recruitment end date

2018-05-20, 1397/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of melatonin effects on oxidative stress in hemodialysied patient, A prospective, randomized, double-blind, controlled trial

Public title

Evaluation of melatonin effects on oxidative stress in hemodialysied patient

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients should be at least two months before the start of the study are under dialysis Patients should not have smoking Principles of dialysis and dialysis person, long-term drug therapy during the study needs to be fixed.

Exclusion criteria:

The patient during the study to undergo the surgery pregnancy or breast-feeding during the study

Age

From **15 years** old to **75 years** old

Gender

Both

Phase

2-3

Groups that have been masked

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

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

Melatonin and placebo that were identical in terms of appearance, each in a separate container A and B. A person who does not have a role in intervention storage between two random – intervention and control in the form of block based on age and sex of the individual who conducted by computer, then had no role in the intervention and of the allocation of the container forklift was unprecedented, Type3, random sequence of news, drugs and packaging each package Based on a random list of medicinal created a code. He also lists the codes for the allocation of patients to treatment group. Random sequence until the end of the study in a safe place away from the register box maintenance. Another person who had no role in the intervention and of the infinite sequence of random – news, participants on the basis of the list of codes assigned to the treatment group. This fitted and random allocation until the completion of the statistical analysis of the company's suppliers and loaders stayed hidden.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the following people are blind to treatment allocation: participants, the one who prescribed the medications, Lab staff, who collect laboratory data, and analyst data but the DSMB (data and safety monitoring

Committee) of the type of information assigned intervention. Medications to placebo tablet form and in terms of shape, size, color, taste, smell and packaging similar to melatonin

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Urmia University of Medical Sciences

Street address

Urmia University of Medical Sciences, sero road, Urmia

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2016-11-25, 1395/09/05

Ethics committee reference number

IR.umsu.1395.533

Health conditions studied

1

Description of health condition studied

Chronic renal patients undergoing hemodialysis

ICD-10 code

Z49

ICD-10 code description

Encounter for care involving renal dialysis

Primary outcomes

1

Description

serum Glutathione

Timepoint

At the first of the study, 30 and 60 days after start of melatonin

Method of measurement

eastbiopharm Lab kit

Secondary outcomes

1

Description

Superoxiddismutase

Timepoint

At the first of study, 30 and 60 dayse after start of melatonin

Method of measurement

Nasdox Lab kit of navande salamat

Intervention groups

1

Description

Intervent Patients in the intervention group melatonin or 5-hydroxy trriptamin with a dose of 3 mg daily for l and received orally .Melatonin pill-shaped building was purchased from the company natermade .

Category

Treatment - Drugs

2

Description

Control group: placebo in the control group as well as to patients without markings, packaging, shape, color, size, smell and taste the same in the same dose with melatonin was given the same term and patients under the care of routine.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Talegani Hospital

Full name of responsible person

Afshin Shiva

Street address

Talegani Hospital, Kashani Street, Urmia

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Phone

+98 44 3344 4593

Email

hospital_talegani@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Afshin Shiva

Street address

Sero road, Urmia

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Phone

+98 44 3223 4897

Email

Afshin.shiva@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Zahra Rezai

Position

Pharmacy Student

Latest degree

Master

Other areas of specialty/work

Medical Pharmacy

Street address

Vakili Street, Bahonar Highway, Urmia

City

Urmia

Province

West Azarbaijan

Postal code

5851945858

Phone

+98 44 3672 8966

Email

d.z73rezai@gmail.com

Person responsible for scientific

inquiries

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Zahra Rezai

Position

Pharmacy Student

Latest degree

Master

Other areas of specialty/work

Medical Pharmacy

Street address

Sero road, Urmia University of Medical Science

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Phone

+98 44 3672 8966

Fax

Email

d.z73rezai@gmail.com

West Azarbaijan

Postal code

5714783734

Phone

+98 44 3672 8966

Fax

Email

d.z73rezai@gmail.com

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

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Total non-identifiable data after striking out people share

When the data will become available and for how long

Start the access period of five years after the print the results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Researchers can get data provided in all articles.

From where data/document is obtainable

Send message to: d.zahra73rezaie@yahoo.com

What processes are involved for a request to access data/document

After their introduction in the message sent, the data will be sent to them for up to 30 days.

Comments

Person responsible for updating data

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Zahra Rezai

Position

Pharmacy Student

Latest degree

Master

Other areas of specialty/work

Medical Pharmacy

Street address

Sero road, Urmia University of Medical Science

City

Urmia

Province