

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Effects of Melatonin on ischemia-reperfusion injury and the klotho protein expression in renal transplant patients

Protocol summary

Summary

The aim of this study is to evaluate the effect of melatonin on ischemia-reperfusion injury (IRI) and expression of Klotho protein in kidney transplant patients. The Study included 80 kidney transplant recipients, recruited based on inclusion and exclusion criteria of our study. All the patients should have had been a history of dialysis at least three months. Smoking and cancerous patients were also excluded from the study. Patients were randomly divided into two groups including control group and trial group. In current study all patients are monitored before and after melatonin administration with use of blood samples. primary Blood samples will be collected 28 days before melatonin and placebo administration. Then the trial group will received melatonin and a placebo will administered to the control group with dose of dose of 3mg/day for 4 weeks. As secondary blood samples will be taken 24 hours after surgery. Finally in both groups the serum level of TNF- α , NGAL, nuclear activity rate of NF κ B and the expression of klotho are measured and compared with use of blood samples.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201610203812N5**
Registration date: **2016-11-26, 1395/09/06**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-11-26, 1395/09/06

Registrant information

Name

Amir Ghorbanihaghjo

Name of organization / entity

Biotechnology Research Center, Tabriz University of Medical Sciences, Tabriz 51664, Iran.

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2016-11-21, 1395/09/01

Expected recruitment end date

2017-06-20, 1396/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Melatonin on ischemia-reperfusion injury and the klotho protein expression in renal transplant patients

Public title

Effects of Melatonin on injury caused by transplant process in renal transplant patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: kidney transplant candidate: had a history of dialysis at least 3 months. Exclusion criteria :Patients with inflammatory disease: acute or chronic infection: autoimmune diseases: hepatic insufficiency : diabetes: malignancy :depression : high and low pressure

: seizures : smokers

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz University Of Medical Science

Street address

Tabriz University of Medical Sciences, Daneshgah
Street, Tabriz, Iran

City

Tabriz

Postal code

Approval date

2016-10-10, 1395/07/19

Ethics committee reference number

IR.TBZMED.REC 1395.756

Health conditions studied

1

Description of health condition studied

Kidney Transplant

ICD-10 code

Z94.0

ICD-10 code description

Kidney transplant status

Primary outcomes

1

Description

TNF-a

Timepoint

3 month

Method of measurement

ELISA

2

Description

nuclear NFkB activity

Timepoint

3 month

Method of measurement

ELISA

3

Description

oxidative stress factors

Timepoint

3 month

Method of measurement

spectrophotometric methods

Secondary outcomes

1

Description

klotho gene and protein expression

Timepoint

3 month

Method of measurement

Real-time PCR and western blotting

Intervention groups

1

Description

The trial group will be administered oral melatonin at the dose of 3mg/day for a period of 28 days before kidney transplant.

Category

Prevention

2

Description

The control group will received oral placebo at the dose of 3mg/day for a period of 28 days before kidney transplant.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Nephrology Research Center

Full name of responsible person

Dr Hassan Argani

Street addressNephrology Research Center, Shahid Modarress
Educational Hospital, Shahid Beheshti University of
Medical Sciences, Tehran, Iran**City**

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**Vice Chancellor for Research of Tabriz University of
Medical Sciences, Biotechnology Research Center**Full name of responsible person**

Dr Siavoush Dastmalchi

Street addressBiotechnology Research Center, Daneshgah Street,
Tabriz University of Medical Sciences**City**

Tabriz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding sourceVice Chancellor for Research of Tabriz University of
Medical Sciences, Biotechnology Research Center**Proportion provided by this source****Public or private sector***empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***2****Sponsor****Name of organization / entity**

Nephrology Research Center

Full name of responsible person

Dr Hassan Argani

Street addressNephrology Research Center, Shahid Modarress
Educational Hospital, Shahid Beheshti University of
Medical Sciences**City**

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Nephrology Research Center

Proportion provided by this source**Public or private sector***empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Hassan Argani

Position

professor of Nephrology

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Tabriz University of Medical Science

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Position

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Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Science

Full name of responsible person

Fatemeh Panah

Position

PhD student

Other areas of specialty/work**Street address****City****Postal code****Phone**

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Fax**Email****Web page address**

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty