

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Investigating The effect of melatonin on serum changes of Adropin in patients with diabetic retinopathy

Protocol summary

Study aim

Possibility of reducing serum Adropin levels in patients with diabetic retinopathy by administering melatonin

Design

In this study, using a sample size a total of 40 patients with diabetic retinopathy will be selected. Considering the probability of a fall of about 20% for the studied patients, the total number of subjects will be about 44. A restricted randomization method will be used for randomization. In this randomized clinical trial study, individuals should be matched in terms of age, gender, and BMI.

Settings and conduct

Patients will receive melatonin for 60 days, At the end of the melatonin administration period on day 60, blood samples will be taken from the patients again, which will be used as a blind for final analysis after the serum separation steps at -70 ° C.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with diabetic retinopathy aged 65 to 75 years Exclusion criteria: Patients with uveitis glaucoma and AMD and pseudoexfoliation syndrome, chronic or acute infection, autoimmune disease, HIV and hepatitis positive patients, pregnant women and chronic liver and kidney patients.

Intervention groups

In this study, a total of 40 diabetic retinopathy patients will be studied. Considering the probability of a fall of about 20% for the studied patients, the total number of subjects will be about 44. 22 patients from the group of patients are randomly selected as the negative control group without melatonin and receiving only routine treatment and the remaining 22 will be selected as the treatment group with melatonin in addition to routine treatment and then From the specified sampling steps, serum levels will be analyzed for specified biochemical analyzes

Main outcome variables

Serum Adropin Levels

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211222053481N1**

Registration date: **2022-02-17, 1400/11/28**

Registration timing: **prospective**

Last update: **2022-02-17, 1400/11/28**

Update count: **0**

Registration date

2022-02-17, 1400/11/28

Registrant information

Name

Alireza Javadzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 1336 4666

Email address

javadzadeha@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-20, 1400/12/01

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating The effect of melatonin on serum changes of Adropin in patients with diabetic retinopathy		Placebo Not used
Public title Investigating The effect of melatonin on serum changes of Adropin in patients with diabetic retinopathy		Assignment Parallel
Purpose Supportive		Other design features
Inclusion/Exclusion criteria Inclusion criteria: Patients with diabetic retinopathy Patients without a history of melatonin use Age range 65 to 75 years Exclusion criteria: History of melatonin use History of using antioxidant compounds such as doxium Has not consumed the essential elements with antioxidant properties Antioxidant vitamins such as vitamins C and E. Not consumed		Secondary Ids empty
Age From 65 years old to 75 years old		Ethics committees 1
Gender Both		Ethics committee Name of ethics committee Ethics committee of Tabriz University of Medical Sciences
Phase N/A		Street address Daneshghah Ave. Tabriz University of Medical Sciences
Groups that have been masked • Outcome assessor		City Tabriz
Sample size Target sample size: 44		Province East Azarbaijan
Randomization (investigator's opinion) Randomized		Postal code 5166614766
Randomization description In order to create balance in the number of samples assigned to each of the studied groups, the blocking method is used. This method is based on simple randomization. In this method, we first determine a total sample volume, then randomly assign a set of them to group A and assign the remainder to group B. For this purpose, Random Allocation Software will be used under Windows (Version 1.0). This method is based on determining the total sample size (44 people) and the number of groups ($n = 2$) and then randomly a set of them (22 people) to group A or intervention and the rest (22 people) to group B or Controls are assigned and then one of them is randomly selected without replacement.		Approval date 2022-02-02, 1400/11/13
Blinding (investigator's opinion) Single blinded		Ethics committee reference number IR.TBZMED.REC.1400.1141
Blinding description In this study, two groups of patients, a total of 44 patients with diabetic retinopathy aged 65 to 75 years referred to a charity hospital or eye treatment centers are selected and studied. 22 patients from the group of patients are randomly selected as the negative control group without melatonin and receiving only routine treatment (-Melatonin) and the remaining 22 will be selected as the treatment group (+ Melatonin) with melatonin in addition to routine treatment. Sampling is done before and after both groups, before the start of melatonin consumption and after the end of the course, and the samples are sent to the laboratory as a number (code) to measure the registered parameters and the answers are obtained for each serum number		Health conditions studied 1 Description of health condition studied Diabetic Retinopathy ICD-10 code E08.311 ICD-10 code description Diabetes mellitus due to underlying condition with unspecified diabetic retinopathy
		Primary outcomes 1 Description serum changes of Adropin Timepoint Measurement of serum Adropin levels before intervention and 60 days after melatonin administration Method of measurement ELISA Method
		Secondary outcomes empty

Intervention groups

1

Description

Intervention group: Diabetic patients with retinopathy. In this study, a total of 44 patients with diabetic retinopathy aged 65 to 75 years who are referred to Nikokary hospital is selected. Twenty-two patients will be randomly selected as the intervention group (+ Melatonin). The intervention group will receive 3 mg of oral melatonin capsule (Norm Life Melatonin Vanatonin) for 60 days in addition to their normal and routine treatment. Before the start of melatonin administration and at the end of the study course, on day 60, blood samples will be taken from both intervention and control patient groups. Finally, the collected serums will be biochemically analyzed and the results will be statistically analyzed along with the results obtained from clinical examinations, and finally, the results will be extracted and reported.

Category

Prevention

2

Description

Control group: 22 patients will be randomly assigned to the negative control group without melatonin and only their usual treatment. Blood samples will be taken from both study groups before the start of the study and after the end of the course, ie on the 60th day. Finally, the collected serums will be biochemically analyzed and the results will be statistically analyzed along with the results obtained from clinical examinations, and finally, the results will be extracted and reported.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Nikokari hospital

Full name of responsible person

Alireza Javadzadeh

Street address

Tabriz university of medical sciences, University Ave.

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Phone

+98 41 3336 7977

Email

javadzadeha@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Khosro Adibkia

Street address

Tabriz university of medical science, university Ave.5166614766

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Phone

+98 41 3335 7310

Email

adibkia@tbzmed.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Alireza Javadzadeh

Position

Full professor

Latest degree

Subspecialist

Other areas of specialty/work

Ophthalmology

Street address

Tabriz university of medical sciences, university Ave,

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Phone
+98 41 3442 6078
Email
javadzadeha@tbzmed.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Alireza Javadzadeh
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Ophthalmology
Street address
Tabriz University of Medical Sciences
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
Phone
+98 41 1336 4666
Fax
Email
javadzadeha@tbzmed.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Alireza Javadzadeh
Position

Professor
Latest degree
Subspecialist
Other areas of specialty/work
Ophthalmology
Street address
Tabriz University of Medical Sciences
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
Phone
+98 41 1336 4666
Fax
Email
javadzadeha@tbzmed.ac.ir

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