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)

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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

Public title
Investigating The effect of melatonin on serum changes of Adropin in patients with diabetic retinopathy
Purpose
Supportive
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
Age
From **65 years** old to **75 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **44**
Randomization (investigator's opinion)
Randomized
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.
Blinding (investigator's opinion)
Single blinded
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
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Daneshghah Ave. Tabriz University of Medical Sciences
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
Approval date
2022-02-02, 1400/11/13
Ethics committee reference number
IR.TBZMED.REC.1400.1141

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
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

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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