Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 2026

Evaluation of melatonin tablets in oxidative stress in patients with beta thalassemia major: A double blind placebo controlled, cross over clinical trial

Protocol summary

Study aim
Investigation of effect of melatonin on oxidative stress in patients with major thallassemia

Design
The current study will be a double blind cross-over clinical trial

Settings and conduct
The present study will be a cross-over clinical trial. Initially, half of the 36 patients eligible randomly will be allocated in one of the melatonin treatment or control groups (the first phase of the study - 45 days). After a 2-week washout period (Phase II study), patients who received melatonin will receive placebo, and patients who received placebo will receive melatonin (phase III study - 45 days). The thalassemia ward of Bu Ali Hospital in Sari, Mazandaran, Iran will be the study center

Participants/Inclusion and exclusion criteria
Inclusion criteria : Beta thalassemia major , Cases who are 18 years old or more , Treatment with standard iron chelators at least for two years , An unchanged treatment for 3 previous months before the begining of the study , Serum ferritin level higher than 1000 ng/dL , Sleep quality index (PSQI) < 5 Exclusion criteria : Any change in treatment regime which happened during this study.

Intervention groups
Intervention :receiving 3mg melatonin tab twice in night Control:receiving placebo tablet twice in night

Main outcome variables
Determining of oxidative stress indexes as GSH,CAT,SOD,MDA

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201212049684N1**
Registration date: **2021-10-30, 1400/08/08**
Registration timing: **prospective**

Last update: **2021-10-30, 1400/08/08**
Update count: **0**

Registration date
2021-10-30, 1400/08/08

Registrant information

Name
Ramin Ataee

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 11 3354 3083

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r.ataee@mazums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-11-22, 1400/09/01

Expected recruitment end date
2022-01-21, 1400/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of melatonin tablets in oxidative stress in patients with beta thalassemia major: A double blind placebo controlled, cross over clinical trial

Public title
Evaluation of melatonin tablets in patients with beta thalassemia major
Purpose
Basic scienece
Inclusion/Exclusion criteria
Inclusion criteria:
Beta thalassemia major Cases who are 18 years old or more Treatment with standard iron chelators at least for two years An unchanged treatment for 3 previous months before the beginning of the study Serum ferritin level higher than 1000 ng/dL Sleep quality index (PSQI)<5
Exclusion criteria:
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data and Safety Monitoring Board

Sample size
Target sample size: **36**
Randomization (investigator's opinion)
Randomized
Randomization description
Block Randomization method is used to randomized the patients. For randomization, we visited the www.sealedenvelope.com, then randomization tab and make a list option were selected, the number of intervention groups, sample size, block size (4) were entered the intended locations, then a random list containing the pattern of patient allocation was obtained in two groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo has been made by pharmaceutics department of the pharmacy faculty of Mazandaran University of Medical Sciences, Iran as completely similar to the medication (Melatonin). The bottles (containing the medication or placebo) will be handed in eligible patients by the thalassemia ward's drugstore according to the random allocation list. Patients, physicians, the responsible of the drugstore and the thalassemia ward's nurses will be blind of the groups. Unique codes will be utilized instead of the alphabet to blind the groups.
Placebo
Used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mazandaran University of Medical Sciences
Street address
Km 18 Khazarabad road ,Payambar Azam assmbely ,Mazandaran University of Medical Sciences,Pharmacy School,Sari,Iran
City
Sari
Province
Mazandaran
Postal code
4847193698
Approval date
2020-07-22, 1399/05/01
Ethics committee reference number
IR.MAZUMS.REC.1399.475

Health conditions studied

1

Description of health condition studied
Thalassemia
ICD-10 code
D56.1
ICD-10 code description
بتاتالاسمی ماژور

Primary outcomes

1

Description
Estimating stress oxidative indexes as GSH,CAT,SOD and MDA
Timepoint
before treatment, at the end of Phase1 and at the end of the study
Method of measurement
Tests for oxidative stress with Spectrophotometry

Secondary outcomes

1

Description
improvement of quality of sleep
Timepoint
Before treatment, at the end of Phase1 and at the end of study
Method of measurement
PSQI- Pittsburgh Sleep Quality Index questionnaire

Intervention groups

1

Description
Intervention: Melatonin tablet 3 mg twice at night for 45 days
Category
Treatment - Drugs

2

Description
Control group: Placebo tablet (twice at night) for 45 days
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Bou Ali Sina hospital
Full name of responsible person
Ramin Ataee
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Km 18 ,Khazarabad road,Payambar Azam buildings۹,Mazandaran University of Medical Sciences,Pharmacy School,
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Sponsors / Funding sources

1

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Name of organization / entity
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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
Mazandaran 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
Mazandaran University of Medical Sciences
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Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Informations according to main consequences can be shared
When the data will become available and for how long
available after publishing of the results
To whom data/document is available
Academic staff and general population
Under which criteria data/document could be used
students and the researchers of thallassemia center can refer to documents and assaying their analysis
From where data/document is obtainable
Can be referred to executive of the project or the correspondence of the article or the manager of the thallassemia center
What processes are involved for a request to access data/document
referring to published article or contact with e-mail or phone with the executive or manager of the center during 2 or 3 days it would be possible for availability to documents
Comments