

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 thalassaemia

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 thalassaemia ward of Bu Ali Hospital in Sari, Mazandaran, Iran will be the study center

Participants/Inclusion and exclusion criteria

Inclusion criteria : Beta thalassaemia 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 : 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)

Phone

+98 11 3354 3083

Email address

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 thalassaemia major: A double blind placebo controlled, cross over clinical trial

Public title

Evaluation of melatonin tablets in patients with beta thalassemia major

Purpose

Basic science

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 pharmaceuticals 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

بتانالاسمی مازور

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

Street address

Km 18 ,Khazarabad road,Payambar Azam buildings, Mazandaran University of Medical Sciences, Pharmacy School,

City

Sari

Province

Mazandaran

Postal code

4847193698

Phone

+98 11 3354 3083

Email

raminataee1349@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Majid Saeidi

Street address

Moalem Square, Deputy of Research, Mazandaran University of Medical Sciences

City

Sari

Province

Mazandaran

Postal code

۴۸۱۵۷۳۳۹۷۱

Phone

+98 11 3325 7230

Email

pajhooheshi@mazums.ac.ir

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

Full name of responsible person

Amirhossein Sarkhosh

Position

Student of Pharmacy

Latest degree

A Level or less

Other areas of specialty/work

Pharmacy

Street address

Km18, Khazarabad road, Payambar Azam buildings, Mazandaran University of Medical Sciences, Pharmacy School

City

Sari

Province

Mazandaran

Postal code

4847193698

Phone

+98 11 3354 3083

Email

a.sarkhosh77@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Ramin Ataee

Position

Associate Prof

Latest degree

Ph.D.

Other areas of specialty/work

Pharmacology

Street address

Km 18 Khazarabad ,Payambar Azam building,
Mazandaran University of Medical Sciences ,Pharmacy
School

City

Sari

Province

Mazandaran

Postal code

4847193698

Phone

+98 11 3354 3083

Email

raminataee1349@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Amirhossein Sarkhosh

Position

Student of Pharmacy

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

Street address

Km 18 Khazaraba building,Payambar Azam
buildings,Mazandaran University of Medical
Scieces,Pharmacy School

City

Sari

Province

Mazandaran

Postal code

4847193698

Phone

+98 11 3354 3083

Email

a.sarkhosh77@gmail.com

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 thalassemia 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
thalassemia 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