

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Effects of melatonin supplementation on clinical symptoms, disease activity and serum oxidative factors in patients with systemic lupus erythematosus

Protocol summary

Study aim

Effects of melatonin supplementation on clinical symptoms, disease activity and serum oxidative factors in patients with systemic lupus erythematosus

Design

This study is a randomized double-blind clinical trial carried out in lupus patients referred to the rheumatology clinic of Tabriz University of Medical Sciences. 50 lupus patients are allocated randomly to two groups receiving melatonin (10 mg divided in to two 5 mg) and receiving placebo.

Settings and conduct

rheumatology clinic of Tabriz University of Medical Sciences- patients and main researcher will be blind

Participants/Inclusion and exclusion criteria

patients with systemic lupus erythematosus. Inclusion criteria: having systemic lupus erythematosus according to ACR criteria and rheumatologist diagnosis; eager to participate in study. Exclusion criteria: having other autoimmune diseases, uncontrolled hypertension, diabetes and other endocrine disorders, cardiovascular diseases, chronic renal failure, liver dysfunction, depression, proliferative lupus nephritis, brain involvement, lupus vasculitis, peritonitis, thrombotic thrombocytopenia purpura, severe hemolysis with reticulocyte more than 8%, severe thrombocytopenia (platelet below 40000), ucarditis, endocarditis, lupus pneumonia, alveolar hemorrhage, use of sedations and contraceptives, use of antioxidant and w3 supplements in previous month, smoking and alcohol consumption, allergy to melatonin, pregnancy and lactation.

Intervention groups

Patients were allocated in to intervention group (receiving melatonin 10mg/day) and control group (receiving placebo).

Main outcome variables

Before and after intervention, clinical symptoms are

assessed with physical examination and disease activity is assessed with SLEDAI. Serum total antioxidant capacity and malondialdehyde are assessed with kit.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110708006975N6**

Registration date: **2018-08-24, 1397/06/02**

Registration timing: **prospective**

Last update: **2018-08-24, 1397/06/02**

Update count: **0**

Registration date

2018-08-24, 1397/06/02

Registrant information

Name

Alireza Khabbazi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1337 3966

Email address

khabbazia@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-09-23, 1398/07/01

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effects of melatonin supplementation on clinical symptoms, disease activity and serum oxidative factors in patients with systemic lupus erythematosus

Public title
Effects of melatonin in systemic lupus erythematosus

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Having systemic lupus erythematosus according to ACR criteria and rheumatologist diagnosis Eager to participate in study
Exclusion criteria:

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
permuted block randomization using RAS software

Blinding (investigator's opinion)
Double blinded

Blinding description
participants ;main researcher .

Placebo
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
Golgasht St.
City
Tabriz
Province

East Azarbaijan
Postal code
5166614754
Approval date
2018-07-23, 1397/05/01
Ethics committee reference number
IR.TBZMED.REC.1397.349

Health conditions studied

1

Description of health condition studied
systemic lupus erythematosus

ICD-10 code
M32

ICD-10 code description
Systemic lupus erythematosus (SLE)

Primary outcomes

1

Description
clinical symptoms
Timepoint
before and after intervention
Method of measurement
physician examination

2

Description
disease activity
Timepoint
before and after intervention
Method of measurement
SLEDAI questionnaire

3

Description
Total antioxidant capacity
Timepoint
before and after intervention
Method of measurement
kit

4

Description
malondialdehyde
Timepoint
before and after intervention
Method of measurement
florimetry

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:

Category

Other

2

Description

Control group:

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Emamreza Hospital

Full name of responsible person

Mahammadmahdi Nabatian

Street address

Golgasht St.

City

Tabriz

Province

East Azarbaijan

Postal code

5166614754

Phone

+98 41 3336 9331

Email

mahdi_6684@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Connective Tissue Diseases Research Center, Tabriz
University of Medical Sciences

Full name of responsible person

Alireza Khabbazi

Street address

Emamreza hospital, Golgasht St.

City

Tabriz

Province

East Azarbaijan

Postal code

5166614754

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+98 41 3336 9331

Email

khabbazia@tbzmed.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Connective Tissue Diseases Research Center, 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

Connective Tissue Diseases Research center, Tabriz
University of Medical Sciences

Full name of responsible person

Alireza Khabbazi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Rheumatology

Street address

Emamreza Hospital, Golgasht St.

City

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Province

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Contact

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Abuse is possible.

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

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

Title and more details about the data/document

The data file will be provided after encoding.

When the data will become available and for how long

6 months after printing results.

To whom data/document is available

all persons

Under which criteria data/document could be used

Use is not allowed.

From where data/document is obtainable

Alireza Khabbazi

What processes are involved for a request to access data/document

Send request via email and receive

Comments**Person responsible for updating data****Contact****Name of organization / entity**Connective Tissue Diseases Research Center, Tabriz
University of Medical Sciences**Full name of responsible person**

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