Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 recieving placebo.

Settings and conduct

rheumatology clinic of Tabriz University o 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 accroding to ACR criteria and rheumatologist diagnosis; eager to participate in study. Exclusion criteria: having other autoimmune diseases, uncontrolled hypertention, 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.
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5166614754
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Connective Tissue Diseases Research Center, Tabriz Unversity of Medical Sciences
Full name of responsible person
Alireza Khabbazi
Street address
Emamreza hospital, Golgasht St.
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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 Unversity 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
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Person responsible for updating data

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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