Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

Investigating the Effect of Melatonin on Memory in Multiple Sclerosis Patients: A Clinical Trial

Protocol summary

Study aim

The primary objective of this study is to investigate the effect of melatonin on short-term visual memory in patients with Relapsing-Remitting Multiple Sclerosis (RRMS) at Buali Hospital in Qazvin in 2025.

Design

This study is designed as a Quasi-Experimental trial with a single-group pre-test and post-test design. Only one group of patients receiving melatonin will be evaluated, and visual working memory data will be collected before and after the intervention period.

Settings and conduct

The study will be conducted at Buali Hospital in Qazvin under the supervision of the Research Deputy of Qazvin University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Patients with a definitive diagnosis of Relapsing-Remitting Multiple Sclerosis (RRMS) based on McDonald criteria and confirmed by a specialist physician, aged 18 to 60 years, suffering from short-term memory disorders detectable by pre-test assessment, no use of memory- or sleep-affecting medications in the past month, willing to provide written informed consent, no history of allergy to melatonin, not pregnant or breastfeeding, and with a stable disease condition with no relapse in the last 30 days and be excluded if the inclusion criteria doesnt met.

Intervention groups

This study includes only one intervention group, consisting of 50 randomly selected patients with Relapsing-Remitting MS. These patients will receive 5 mg of melatonin daily, one hour before sleep, for 12 weeks. No control or placebo group is included in this design.

Main outcome variables

Short-term visual memory, measured using the Color Wheel Test. Potential side effects of melatonin, recorded through patient reports and clinical examination. Changes in quality of life, assessed using standard questionnaires.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251006067522N1**
Registration date: **2025-10-29, 1404/08/07**
Registration timing: **prospective**

Last update: **2025-10-29, 1404/08/07**
Update count: **0**

Registration date

2025-10-29, 1404/08/07

Registrant information

Name

Kavosh Ansari Dezfoli

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 937 538 6185

Email address

k.ansaridezfoli@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-11-22, 1404/09/01

Expected recruitment end date

2026-02-20, 1404/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Effect of Melatonin on Memory in Multiple Sclerosis Patients: A Clinical Trial

Public title
Effect of Melatonin on Memory in Multiple Sclerosis Patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Definitive diagnosis of MS based on McDonald criteria and confirmed by a specialist physician. Age between 18 and 60 years. Diagnosis of Relapsing-Remitting Multiple Sclerosis (RRMS). Suffering from short-term memory disorders detectable by pre-test assessment.

Exclusion criteria:
Age less than 18 years or more than 60 years. Lack of written patient consent to participate in the study. Diagnosis of MS types other than Relapsing-Remitting MS (RRMS). Use of other medications that may affect memory or sleep. History of allergy or sensitivity to melatonin. Presence of other chronic conditions such as uncontrolled diabetes or kidney failure. Alcohol or drug use in the past 6 months. Pregnancy or breastfeeding

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Qazvin University of Medical Sciences

Street address
Building No. 12, Bu-Ali Street, Qazvin, Qazvin Province, 34197, Iran

City
Qazvin

Province
Qazvin

Postal code
34119759811

Approval date
2025-08-26, 1404/06/04

Ethics committee reference number
IR.QUMS.REC.1404.165

Health conditions studied

1

Description of health condition studied
Multiple Sclerosis (Relapsing-Remitting Type)

ICD-10 code
G35

ICD-10 code description
Multiple sclerosis

Primary outcomes

1

Description
Short-term visual memory Description: Short-term visual memory is measured using the Colour Wheel Test. This variable refers to the patients' ability to recall and reproduce colours within a short time frame (a few seconds to a few minutes), with evaluation criteria including error rate, response time, and confidence in colour selection.

Timepoint
Measurement of outcome variables will be conducted at two time points: initially, before the intervention (pre-test) and then 12 weeks after the start of melatonin use (post-test).

Method of measurement
Short-term visual memory: Measured using the Colour Wheel Test, which involves selecting colours on a simulated display screen, with criteria including error rate, response time, and confidence in selection.

2

Description
Potential side effects of melatonin are recorded through patient reports and clinical examinations by healthcare staff. This variable includes any physical or psychological symptoms reported by patients during the intervention period.

Timepoint
Measurement of outcome variables will be conducted at two time points: initially, before the intervention (pre-test) and then 12 weeks after the start of melatonin use (post-test).

Method of measurement
Recorded through patient verbal reports and clinical examinations by healthcare staff.

3

Description
Changes in quality of life are assessed using standard questionnaires (such as health-related quality of life questionnaires). This variable reflects improvements or reductions in general well-being, daily functioning, and patient satisfaction with life.

Timepoint
Measurement of outcome variables will be conducted at two time points: initially before the intervention (pre-test) and then 12 weeks after the start of melatonin use (post-test).

Method of measurement
Changes in quality of life: Assessed using standard health-related quality of life questionnaires (e.g., SF-36).

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Melatonin administration: Patients receive 5 mg of melatonin daily, one hour before sleep, for 12 weeks.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Qazvin Boali Hospital

Full name of responsible person
Kavosh Ansari Dezfoli

Street address
Building No. 12, Bu-Ali Street, Qazvin, Qazvin Province, 34197, Iran

City
Qazvin

Province
Qazvin

Postal code
15315-34199

Phone
+98 28 3333 6001

Email
info@qums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Qazvin University of Medical Sciences

Full name of responsible person
Seyed Hossein Mirhashemi

Street address
Building No. 12, Bu-Ali Street, Qazvin, Qazvin Province, 34197, Iran

City
Qazvin

Province
Qazvin

Postal code
15315-34199

Phone
+98 28 3333 6001

Email
info@qums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Qazvin 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
Qazvin University of Medical Sciences

Full name of responsible person
Kavosh Ansari Dezfoli

Position
Neurology Resident

Latest degree
Medical doctor

Other areas of specialty/work
Neurology

Street address
Building No. 12, Bu-Ali Street, Qazvin, Qazvin Province, 34197, Iran

City
Qazvin

Province
Qazvin

Postal code
1531534199

Phone
+98 937 538 6185

Fax

Email
k.ansaridezfoli@qums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Qazvin University of Medical Sciences

Full name of responsible person
Kavosh Ansari Dezfoli

Position
Neurology Resident

Latest degree
Medical doctor

Other areas of specialty/work
Neurology

Street address
Building No. 12, Bu-Ali Street, Qazvin, Qazvin Province, 34197, Iran

City
Qazvin

Province
Qazvin

Postal code
1531534199

Phone
+98 937 538 6185

Fax

Email
k.ansaridezfoli@qums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Qazvin University of Medical Sciences

Full name of responsible person
Kavosh Ansari Dezfoli

Position
Neurology Resident

Latest degree
Medical doctor

Other areas of specialty/work
Neurology

Street address
Building No. 12, Bu-Ali Street, Qazvin, Qazvin Province, 34197, Iran

City
Qazvin

Province
Qazvin

Postal code
1531534199

Phone
+98 937 538 6185

Fax

Email
k.ansaridezfoli@qums.ac.ir

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
Yes - There is a plan to make this available

Title and more details about the data/document
The data within the document includes aggregated study design information, inclusion/exclusion criteria, primary outcome variables, and initial IRCT registration details. Due to ethical considerations and privacy concerns, individual participant data (e.g., memory test results or personal details) cannot be fully shared; only de-identified data related to primary outcomes (e.g., Colour Wheel Test results) can be provided after receiving approval from the Qazvin University of Medical Sciences Ethics Committee and complying with institutional policies. The document also contains a CRS system link and preliminary IRCT registration information, indicating the clinical trial registration process.

When the data will become available and for how long
The access period for the data/document will begin 6 months after the publication of the study results, anticipated to be around mid-April 2026, and will remain available for 5 years thereafter.

To whom data/document is available
Access to the data or document is allowed for researchers affiliated with accredited academic or scientific institutions. These individuals must submit a formal request with identification documents and a description of their research aims, while following ethical guidelines and privacy laws.

Under which criteria data/document could be used
The data or document may only be used for academic research purposes, including statistical analysis, replication studies, and scientific investigations related to the effect of melatonin on memory in patients with multiple sclerosis. Usage conditions include obtaining ethical approval from the Qazvin University of Medical Sciences Ethics Committee, signing a confidentiality and data use agreement, and ensuring that no participant can be re-identified. Applicants must submit a written request outlining their research objectives, analysis.

From where data/document is obtainable
Applicants seeking access to the data or documents should first contact the Principal Investigator, Dr. Hossein Mozhdehipanah, via email (hmozhdehipanah@qums.ac.ir) or phone (09123040087). If there is no response, they are advised to reach out to the Research Deputy of Qazvin University of Medical Sciences through the website or by phone (028-33336001). Additionally, the IRCT support system can be contacted via email (irct@iums.ac.ir) if necessary. Priority is given to official email communication, and a written request with the necessary documentation must be submitted.

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

The process for requesting data/documents is as follows: The applicant must submit a written request, including research objectives, analysis methods, and identification documents, to the Principal Investigator's email (hmozhdehipanah@qums.ac.ir). The request will be reviewed by the Principal Investigator and referred to the Qazvin University of Medical Sciences Ethics Committee for ethical approval (approximate duration: 1-2 weeks). Upon ethical approval, the applicant must sign a confidentiality and data use agreement. After completing the agreement, the de-identified data will be provided securely (e.g., encrypted file) via email or the university's secure platform. In case of issues, the applicant may contact the Research Deputy or IRCT support (irct@iums.ac.ir). The entire process typically takes 2-3 weeks, contingent on complete documentation and compliance with regulations.

Comments