

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Efficacy and Safety of Sublingual Melatonin in alleviation of IBS Symptoms

Protocol summary

Study aim

The aim of present study is to determine whether using sublingual melatonin tablet will improve the quality of life in IBS patients

Design

Design of the study is a triple-blind, placebo-controlled, randomized control single center clinical trial. Patients with age more than 18 years old with IBS will be enrolled the study. Patients whom are not desired to enroll the study will be excluded. In this research, 76 eligible patients with IBS compatible with inclusion criteria were chosen. patients were randomly divided into two control and intervention groups by Microsoft Excel software. and a code was allocated to each one of them.

Settings and conduct

This study is conducted as placebo controlled double blinded randomized clinical trial in taleqani hospital participants and researcher all has been blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: IBS patients with age more than 18 years old Exclusion criteria: pregnancy and breastfeeding

Intervention groups

Intervention group (sublingual melatonin tablet): IBS patients compatible with inclusion/exclusion criteria administrated with 3 mg sublingual melatonin daily for 8 weeks. Control group (sublingual melatonin tablet placebo): IBS patients compatible with inclusion/exclusion criteria administrated with 1 tablet of placebo daily for 8 weeks.

Main outcome variables

Change in QOL34 score 8 weeks after usage of sublingual melatonin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20121021011192N14**

Registration date: **2023-05-29, 1402/03/08**

Registration timing: **prospective**

Last update: **2023-05-29, 1402/03/08**

Update count: **0**

Registration date

2023-05-29, 1402/03/08

Registrant information

Name

Mohammad Abbasinazari

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8887 3704

Email address

m_abbasi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-22, 1402/04/01

Expected recruitment end date

2023-10-23, 1402/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy and Safety of Sublingual Melatonin in alleviation of IBS Symptoms

Public title

Efficacy and Safety of Sublingual Melatonin in alleviation

of irritable Bowel

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients above 18 years old with complaint of lower abdominal pain and changes in defecation more than three months obtaining consent form for entry the study
Exclusion criteria:
Pregnant or breastfeeding women Patients with Kidney injury (AKIN classification stage 3)

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **76**

Randomization (investigator's opinion)
Randomized

Randomization description
1:1 randomization, centralized web-based randomization and according to the entry and exit criteria, through random allocation by balanced block method, individuals are divided into two groups of control and experimental. Using Random Sequence Generator, groups are created and people are placed in one of these two groups based on the reference sequence.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants, principle investigator, healthcare providers (Physicians, nurses) who care for participants during the trial, data collectors and outcome assessors all are blinded by providing placebo sublingual tablet in same size, shape color, odor and package with sublingual tablet of melatonin which organized just by one responsible co-researcher has no involvement in running study.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of pharmacy, nursing and midwifery of Shahid Beheshti university of medical science

Street address

School of Pharmacy, Nyayesh junction, Valiasr street

City
Tehran
Province
Tehran
Postal code
1996835113
Approval date
2023-05-28, 1402/03/07
Ethics committee reference number
IR.SBMU.PHARMACY.REC.1402.021

Health conditions studied

1

Description of health condition studied

Irritable Bowel Syndrom

ICD-10 code

K58

ICD-10 code description

Irritable bowel syndrome

Primary outcomes

1

Description

Score of quality of life on the basis of IBS-QOL34

Timepoint

Before intervention and 4 weeks after initiation of use of melatonin

Method of measurement

QOL34 questionarre

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Sublingual administration of 3 miligram of melatonin daily for 8 weeks

Category

Treatment - Drugs

2

Description

Control group: Sublingual administration of melatonin placebo tablet daily for 8 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

School of pharmacy, Shahid Behesti University of
Medical Sciences

Full name of responsible person

Mohammad Abbasinazari

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valiasr street no 217

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Hassan Yazdanpanah

Street address

School of Pharmacy, Nyayesh junction, Valiasr street

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yazdanpanah@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mohammad Abbasinazari

Position

full professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Person responsible for updating data

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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

Undecided - It is not yet known if there will be 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

کل داده ها بالقوه پس از غیر قابل شناسایی کردن افراد قابل اشتراک گذاری است

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

for people working in academic institutions

Under which criteria data/document could be used

general use

From where data/document is obtainable

email to: m_abbasi@sbmu.ac.ir

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

10 working days after receiving request email

Comments