Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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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 irratable Bowel

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients above 18 years old with compliant 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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+98 21 8866 5282

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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

Contact

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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 recieving request email

Comments