Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

Determination of the melatonin effect on gastrointestinal symptoms and quality of life in patients with irritable bowel syndrome with and without sleep disorders

Protocol summary

Study aim
Comparison of the melatonin effect on gastrointestinal symptoms and quality of life in irritable bowel syndrome patients with and without sleep disorders

Design
Double blind randomised _ paralled clinical trial which participants randomly allocated to control (n=68) and melatonin supplementation groups(n=68)

Settings and conduct
In this study, patients referred to Imam Reza Hospital, after the definitive diagnosis of irritable bowel syndrome, using the ROME 4 diagnosis index, enter the study if they complete the informed consent form. According to the PSQI sleep questionnaire, patients were divided into two groups with and without sleep disorders. Each group are randomly divided into control and paralled groups, and the paralled group will receive 2 melatonin 3 mg tablets and the control group received two placebo.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients diagnosed with irritable bowel syndrome based on ROME 4 diagnostic index. According to the PSQI sleep questionnaire, they are with and without sleep disorders. Exclusion criteria: depression, history of bowel surgery, dietary supplements and herbal remedies

Intervention groups
Paralled group will receive 2 melatonin 3 mg tablets every 12 hours.The control group also will receive two placebo pills every 12 hours.

Main outcome variables
In this study, the effects of melatonin tablets on the severity of abdominal pain, bloating intensity, stool form, quality of life (Based on a valid quality of life questionnaire in patients with irritable bowel syndrome), sleep quality (Based on PSQI sleep quality questionnaire) in patients with irritable bowel syndrome will be evaluated in comparison with the control group.

General information

Reason for update

Acronym
IBS

IRCT registration information
IRCT registration number: **IRCT20220104053626N2**
Registration date: **2022-02-13, 1400/11/24**
Registration timing: **registered_while_recruiting**

Last update: **2022-02-13, 1400/11/24**
Update count: **0**

Registration date
2022-02-13, 1400/11/24

Registrant information

Name
Masood Dinevari

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-01-20, 1400/10/30

Expected recruitment end date
2022-04-18, 1401/01/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Determination of the melatonin effect on gastrointestinal symptoms and quality of life in patients with irritable bowel syndrome with and without sleep disorders

Public title
comparison of the melatonin effect in irritable bowel syndrome patients

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
being satisfied to participate in the study Patients with definitive diagnosis of IBS based on ROME 4 questionnaire, with sleep disorders diagnosed based on PSQI questionnaire. Patients with definitive diagnosis of IBS based on ROME 4 questionnaire, without sleep disorders

Exclusion criteria:
Previous history of diagnosed gastrointestinal diseases including IBD Intestinal surgery Depression Receive herbal medicines

Age
No age limit

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **136**

Randomization (investigator's opinion)
Randomized

Randomization description
Among the patients who volunteered to participate in the study, 136 people will be selected by simple random sampling. Randomization method: block Randomization unit: individual Random layers: In each block, people will be matched based on age and gender. Random allocation tool: Random allocation software How to build a random sequence: Using Random allocation software Concealment: A random sequence created in a safe place and performed by an independent person not involved in the trial during the study. Random allocation of hidden individuals, patients and researchers will not be aware of it.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is a double-blind study in which the researcher of this study and the patients participating in the study will be unaware of the type of supplement received. The supplements will be provided to patients by another person who has no role in completing the questionnaire. They will also be informed of the existence of two types of supplements (melatonin and placebo) when obtaining consent, but will be unaware of which study groups they will be in. Placebo tablets are similar in appearance, color, and size to melatonin tablets.

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
Tabriz University of Medical Sciences, Daneshgah St, Golgasht St.

City
Tabriz

Province
East Azarbaijan

Postal code
5166614766

Approval date
2021-08-01, 1400/05/10

Ethics committee reference number
IR.TBZMED.REC.1400.387

Health conditions studied

1

Description of health condition studied
Irritable Bowel Syndrome

ICD-10 code
K58

ICD-10 code description
Irritable bowel syndrome

Primary outcomes

1

Description
Abdominal pain severity based on a questionnaire on a percentage scale,From zero with an increase of 25 units

Timepoint
Before and after the intervention

Method of measurement
Irritable Bowel Syndrome Symptoms Severity Questionnaire

2

Description
Quality of life based on the quality of life questionnaire

for patients with irritable bowel syndrome

Timepoint

Before and after the intervention

Method of measurement

the quality of life questionnaire for patients with irritable bowel syndrome

3

Description

Intensity of bloating based on a questionnaire as a percentage scale,From zero with an increase of 25 units

Timepoint

Before and after the intervention

Method of measurement

Irritable Bowel Syndrome Symptoms Severity Questionnaire

4

Description

Stool form

Timepoint

Before and after the intervention

Method of measurement

Irritable Bowel Syndrome Symptoms Severity Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Melatonin. Patients in the intervention group who will take two melatonin 3 mg tablets daily (manufactured by Zahravi Pharmaceutical Company) for two months during the study.

Category

Treatment - Other

2

Description

Control group: Control group: placebo. Patients in the placebo group who will take two placebo tablets daily (manufactured by Zahravi Pharmaceutical Company) during two months of study.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam reza hospital

Full name of responsible person

Farzaneh Jafarzadeh

Street address

Emam reza hospital, Golgast st,Tabriz.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

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

Tabriz University of Medical Sciences

Full name of responsible person

Masood Dinevari

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

No - There is not 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

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable