Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Dec 2023

Effect of Bee Food Supplement Propolis on Food intake, Severity of disease and Quality of life in Patients with Irritable Bowel Syndrome (based on RomeIV criteria): a Randomized Double-Blind Clinical Trial

Protocol summary

Study aim
Effect of Bee Food Supplement Propolis on Food intake, Severity of disease and Quality of life in Patients with Irritable Bowel Syndrome (based on RomeIV criteria)

Design
A randomized double-blind clinical trial, a parallel group design of 52 patients, followed for six weeks.

Settings and conduct
Participants will be recruited from outpatients attending Soroush Special Clinic in Ahvaz city, Iran.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients diagnosed irritable bowel syndrome with Rome IV criteria, fill out written consent form, having no allergy to bee products Non-arrival conditions: having pregnancy or lactation, having malignancy or other chronic diseases of the gastrointestinal tract, having regular use of gastrointestinal modifying drugs, having regular use of laxatives, having a history of major surgery in the digestive system, following dietary plans, having a regular daily intake of Prebiotic / Probiotics, consumption of antibiotics, usage of psychotherapeutic drugs, including depression and anxiety drugs.

Intervention groups
Propolis extract at a dose of 500 mg per day for six weeks. Control group: Placebo at a dose of 500 mg per day for four consecutive months

Main outcome variables
Food intake, Severity of disease and Quality of life in patients with Irritable Bowel Syndrome

General information

Reason for update
Sampling ends with a longer period of time.

Acronym

IRCT registration information
IRCT registration number: **IRCT20190708044154N1**
Registration date: **2019-12-26, 1398/10/05**
Registration timing: **registered_while_recruiting**

Last update: **2020-02-13, 1398/11/24**
Update count: **1**

Registration date
2019-12-26, 1398/10/05

Registrant information

Name
Mahsa Miryan

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 41 3335 7584

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-07-31, 1398/05/09

Expected recruitment end date
2020-06-18, 1399/03/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of Bee Food Supplement Propolis on Food intake, Severity of disease and Quality of life in Patients with Irritable Bowel Syndrome (based on RomeIV criteria): a

Randomized Double-Blind Clinical Trial

Public title
Effect of Bee Food Supplement Propolis on Food intake, Severity of disease and Quality of life in Patients with Irritable Bowel Syndrome (based on RomeIV criteria): a Randomized Double-Blind Clinical Trial

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Patients diagnose irritable bowel syndrome with Rome IV criteria Filling out the written consent form Not having allergy to bee products

Exclusion criteria:
Pregnant or lactating women Cases of malignancy or other chronic digestive diseases such as inflammatory bowel disease and celiac disease Regular use of drugs that modify gastrointestinal movements such as metoclopramide, cisapride, narcotics, diphenoxylate, etc. Regular use of laxatives History of major surgery in the digestive system (including Billroth's operating, having any Ostomy and resection of any part of the digestive tract). Following diet plans Individuals with daily and regular use of Prebiotic/ probiotic compounds Consumption antibiotics People who use psychotherapeutic drugs, including depression and anxiety.

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **52**

Randomization (investigator's opinion)
Randomized

Randomization description
Stratified block randomization, The type of blindness in our study will be double-blind. Prior to the onset of the study, the box containing the relevant pills is coded A and B by Pharmacist, in order to blind the researcher about which supplement each group received. In this study, the patients and researchers will not be aware of the allocation concealment until the end of the study.

Blinding (investigator's opinion)
Double blinded

Blinding description
Except pharmacist, none of the participants and researchers will be aware of them until the end of the study.

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, Attar Neishabouri Avenue, Golgasht Street.

City
Tabriz

Province
East Azarbaijan

Postal code
5166/15731

Approval date
2019-07-28, 1398/05/06

Ethics committee reference number
IR.TBZMED.REC.1398.473

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
severity of Irritable bowel syndrome

Timepoint
At the beginning of the study and the sixth week of the intervention

Method of measurement
IBS Severity Index(IBSSI)

Secondary outcomes

1

Description
Quality of life in Patients with Irritable Bowel Syndrome

Timepoint
At the beginning of the study and the sixth week of the

intervention

Method of measurement

Irritable Bowel Syndrome Quality of Life questionnaire (IBS-QOL)

2

Description

Food intake in Patients with Irritable Bowel Syndrome

Timepoint

At the beginning of the study and the sixth week of the intervention

Method of measurement

3-Day Food Intake Record

Intervention groups

1

Description

Intervention group: Propolis extract at a dose of 500 mg per day for six weeks, taking 2 tablets daily.

Category

Treatment - Drugs

2

Description

Control group: Placebo at a dose of 500 mg per day for six consecutive weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Soroush Special Clinic

Full name of responsible person

Pezhman Alavinejad

Street address

West Soroush Avenue, Kianpars.

City

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Phone

+98 61 3333 7908

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Pezhmanalavinejad@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Alireza Ostadrahimi

Street address

Health and Nutrition Faculty, Tabriz University of Medical Sciences, Attar Neishabouri Avenue, Golghast Street.

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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

Mahsa Miryan

Position

Masters student in Clinical Nutrition

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Dr Alireza Ostadrahimi

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
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Person responsible for updating data

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Name of organization / entity
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Position
Masters student in Clinical Nutrition

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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
Yes - There is a plan to make this available

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

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
The non-identifiable individual participant data collected in this study will be shared. Also, The protocol, results, and statistical analysis of the current study will be published in the relevant articles.

When the data will become available and for how long
The non-identifiable individual participant data will become available after the publication of the relevant articles.

To whom data/document is available
The non-identifiable individual participant data will become available to other researchers in academic institutions.

Under which criteria data/document could be used
The data of the present study will only be accessible by other researchers, for conducting Meta analysis.

From where data/document is obtainable
The researchers (student and her supervisor)

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

Comments