Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The Effect of Piloshot Capsule on Symptom Severity and Emotional Status in Patients with Chronic Fatigue Syndrome: A Randomized Double-Blind Placebo-Controlled Clinical Trial

Protocol summary

Study aim

To evaluate the effect of Piloshot capsule on symptom improvement and emotional status in patients with chronic fatigue syndrome

Design

This is a randomized, double-blind, parallel-group, controlled, phase 3 clinical trial conducted on 50 patients. For randomization in this study, the allocation sequence will be generated using R software (version 4.2.2) with block randomization (block sizes of 4 and 6).

Settings and conduct

This randomized double-blind placebo-controlled clinical trial enrolls 50 patients randomly allocated into two 25-subject groups. Medication allocation is coded by an independent head nurse.Assessments using DASS-21 questionnaire are conducted at baseline and weeks 4, 8, and 12, with data analyzed using SPSS version 30. Blinding of patients, physicians, and technicians is maintained using matched placebos and coding.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Confirmed diagnosis of Chronic Fatigue Syndrome based on international criteria,Age between 18-65 years,Willing and able to complete study questionnaires,Signed informed consent form Exclusion Criteria: Active medical conditions such as untreated hypothyroidism or severe sleep apnea, History of major psychiatric disorders (schizophrenia, bipolar disorder), Use of CNS-affecting medications, Pregnancy or lactation,History of substance abuse within past 6 months

Intervention groups

The intervention group will receive two 500 mg Piloshot capsules daily (morning and evening) for 8 weeks.The control group will receive an identical placebo in appearance, color, and packaging, following the same dosing schedule.All participants will receive standardized medication instructions.Treatment adherence will be monitored through:Pill count of remaining capsules. Daily patient self-reports of medication intake

Main outcome variables

Severity of chronic fatigue syndrome symptoms,DASS-21 questionnaire score

General information

Reason for update

Acronym

PSC

IRCT registration information

IRCT registration number: **IRCT20250802066731N1**
Registration date: **2025-08-09, 1404/05/18**
Registration timing: **prospective**

Last update: **2025-08-09, 1404/05/18**
Update count: **0**

Registration date

2025-08-09, 1404/05/18

Registrant information

Name

Ali وحیدی

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3329 5570

Email address

a.vahidi@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-08-31, 1404/06/09

Expected recruitment end date

2026-03-18, 1404/12/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Piloshot Capsule on Symptom Severity and Emotional Status in Patients with Chronic Fatigue Syndrome: A Randomized Double-Blind Placebo-Controlled Clinical Trial

Public title

The Effect of Piloshot Capsule on Symptoms and Emotional Status in Patients with Chronic Fatigue Syndrome: A Randomized Double-Blind Clinical Trial

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Definitive diagnosis of Chronic Fatigue Syndrome based on the Chronic Fatigue Syndrome Questionnaire Age above 18 years and below 65 years

Exclusion criteria:

Active medical conditions that could explain chronic fatigue (e.g., untreated hypothyroidism, sleep apnea, narcolepsy, drug side effects) Unresolved prior medical diagnoses (e.g., chronic hepatitis, malignancies) Current or history of psychiatric disorders (e.g., major depressive disorder with psychotic/melancholic features, bipolar disorder, schizophrenia, anxiety disorders, dementia, eating disorders) Use of medications that may interfere with study results or cannot be safely discontinued Pregnancy or lactation Non-compliance with study follow-up Tobacco use, alcohol consumption, or substance abuse

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

n this study, the random sequence will be generated using R software version 4.2.2 with block randomization (block sizes of 4 and 6). Participants will be randomly allocated using sequentially numbered sealed envelopes to either the intervention group (receiving Piloshot capsule) or control group (receiving placebo). Outcome assessments will be conducted in a double-blind manner by both researchers and participants, with allocation codes maintained by an independent statistics unit."

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, both participants and assessing researchers will remain unaware of the assigned treatment (Piloshot or placebo).The intervention and placebo capsules will be designed to be identical in appearance, color, odor, and packaging.allocation information will be accessible only to the independent statistician who will not participate in treatment or evaluation procedures.Allocation codes will remain concealed until completion of final data analysis.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Zahedan University of Medical Sciences

Street address

Medical Sciences Campus, Zahedan University of Medical Sciences, "Professor Habibollah Hosseini Square

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Approval date

2025-07-18, 1404/04/27

Ethics committee reference number

IR.ZAUMS.REC.1404.154

Health conditions studied

1

Description of health condition studied

Chronic Fatigue Syndrome

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Severity of chronic fatigue syndrome symptoms

Timepoint

Baseline (pre-intervention) - Week 4 post-treatment - Week 8 post-treatment - Week 12 post-treatment

Method of measurement

Standardized fatigue severity questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Treatment Group : Receives: 2 Piloshot capsules (500 mg each, produced by BSK Pharmaceutical Company) daily Dosage: 1 capsule in morning + 1 capsule in evening Duration: 8 weeks of continuous treatment .

Category

Treatment - Drugs

2

Description

Control group: Receives: Placebo (manufactured by Mashhad University of Medical Sciences School of Pharmacy) Matching: Identical in shape, color, and packaging to active drug Schedule: Same dosing regimen as treatment groupStudy Procedures Randomization & Blinding:Treatment assignment by independent head nurse Secure coding system implementation Double-blind maintenance (participants & investigators)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Baharan Psychiatric Hospital

Full name of responsible person

Ali Vahidi

Street address

Baharan Psychiatric Teaching Hospital, Imam Khomeini Ave., Across from Grain Storage Facility

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9819713955

Phone

+98 54 3351 3778

Email

a.vahidi@zaums.ac.ir

Web page address

https://baharan.zaums.ac.ir/cantact

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Alireza Ansari Moghaddam

Street address

School of Medicine, Zahedan University of Medical Sciences, Persian Gulf Blvd., Zahedan, Iran

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Phone

+98 54 3337 2116

Email

ansariaLireza@yahoo.com

Web page address

https://research.zaums.ac.ir/

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Ali Vahidi

Position

Resident of Psychiatry

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

Street address

Baharan Psychiatric Teaching Hospital, Imam Khomeini Ave., Across from Grain Storage Facility

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code
9819713955

Phone
+98 54 3351 3778

Email
a.vahidi@zaums.ac.ir

Web page address
https://baharan.zaums.ac.ir/cantact

Person responsible for scientific inquiries

Contact

Name of organization / entity
Zahedan University of Medical Sciences

Full name of responsible person
Ali Vahidi

Position
"Resident of Psychiatry"

Latest degree
Medical doctor

Other areas of specialty/work
Psychiatrics

Street address
Baharan Medical Center, Imam Khomeini Ave., Across from Grain Storage Facility

City
Zahedan

Province
Sistan-va-Balouchestan

Postal code
9819713955

Phone
+98 54 3351 3778

Email
a.vahidi@zaums.ac.ir

Web page address
https://baharan.zaums.ac.ir/cantact

Person responsible for updating data

Contact

Name of organization / entity
Zahedan University of Medical Sciences

Full name of responsible person
Ali Vahidi

Position
Resident of Psychiatry

Latest degree
Medical doctor

Other areas of specialty/work
Psychiatrics

Street address
Baharan Psychiatric Hospital, Imam Khomeini Street, Opposite Wheat Silo

City
Zahedan

Province
Sistan-va-Balouchestan

Postal code
9819713955

Phone
+98 54 3351 3778

Email
a.vahidi@zaums.ac.ir

Web page address
https://baharan.zaums.ac.ir/cantact

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
Participants will be coded to facilitate data access and management; however, only primary outcomes will be published, and no individual participant data will be disclosed under any circumstances."

When the data will become available and for how long
6 months after publication of the results

To whom data/document is available
General Use

Under which criteria data/document could be used
Here are professional ways to reference ethical compliance in your manuscript:

From where data/document is obtainable
Electronic mail

What processes are involved for a request to access data/document
The requester must first send an email message explaining the purpose of data usage. Within one week, the information will be sent to the applicant with applicable terms and restrictions.

Comments