

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

comparison the effect of hydro alcoholic extract of Nardostachys jatamansi DC with the effect of hydro alcoholic extract of Nardostachys jatamansi DC with Dompridon® on the symptoms of patients with functional dyspepsia® on the symptoms of patients with functional dyspepsia/post prandial distress syndrome.

Protocol summary

Summary

This Double-Blind, Phase 0 trial ,will be done to compare the effect of Nardostachys jatamansi DC with Dompridon® on decreasing the severity of symptoms in patients with functional dyspepsia.A total number of 128 ,25 to 60 years-old patients with functional dyspepsia according to Roman criteria 3 that selected by a specialist physician from the referred patients to the Liver and Gastrointestinal Diseases Clinic , entered into the study after obtaining informed consent. patient with a history of use any chemical or herbal drug with the gastrointestinal effects and pregnant women will be excluded. patients All patients will randomly divided into two groups with use of a table of random digits. In the intervention group patients will receive hydro-alcoholic extract powder of Nardostachys jatamansi DC capsules ,500 milligrams, three times in a day half-hour before each meal .In the control group Domperidone capsule of Abidi company (Motidon), 10 milligrams ,three times in a day half-hour before each meal will prescribe.Capsules are completely compatible in two groups and patients are not aware of the type of medication. Duration of treatment was 4 weeks in both groups and the Gastrointestinal symptoms rating scale questioner was completed before, 2nd and 4th weeks of treatment as well as one month after the end of the treatment. All primary data and outcomes are collected and recorded by the Assistant of Traditional Medicine using In-person and telephone interviews. Analysis of the information during the study and, finally, by the statistics consultant and without the knowledge of the type of allocation of drugs to the two groups will be done.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017022332738N1**

Registration date: **2017-11-12, 1396/08/21**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-11-12, 1396/08/21

Registrant information

Name

Mohaddese Mirzapour

Name of organization / entity

Babol University of Medical sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology of Babol University of Medical Sciences

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-03-21, 1397/01/01

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
comparison the effect of hydro alcoholic extract of Nardostachys jatamansi DC with the effect of hydro alcoholic extract of Nardostachys jatamansi DC with Dompridon® on the symptoms of patients with functional dyspepsia® on the symptoms of patients with functional dyspepsia/post prandial distress syndrome.

Public title
Effect of Nardostachys jatamansi DC on clinical symptoms of functional dyspepsia /postprandial distress syndrome.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: patients aged 25 to 60 years; with a diagnosis of functional dyspepsia (based on ROME III criteria) and no history of peptic ulcer and reflux disease; normal endoscopic with no specific pathologic finding and H. pylori negative; no treatment before the current study(new patient); there is no underlying medical conditions; including heart failure; kidney failure and uremic disease; cirrhosis; diabetes; hypothyroidism and hyperthyroidism; no history of abdominal surgery; no history of chemotherapy and radiation or exposure radioactive radiation. Exclusion criteria: use of chemical and herbal drugs with gastrointestinal effects; pregnancy and lactation; patients disagreement to continue the project and lack of access to patients

Age
From **25 years** old to **60 years** old

Gender
Both

Phase
0

Groups that have been masked
No information

Sample size
Target sample size: **128**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Babol University of Medical Sciences

Street address

Daneshgah sq.,Ganjafroz st., Keshvari St.

City

Babol

Postal code

Approval date

2016-12-26, 1395/10/06

Ethics committee reference number

MUBABOL.REC.1395.200

Health conditions studied

1

Description of health condition studied

functional dyspepsia

ICD-10 code

K30

ICD-10 code description

Dyspepsia

Primary outcomes

1

Description

total score of gastrointestinal symptom rating scale

Timepoint

before intervention , the second and fourth weeks of the intervention, one month after the end of intervention

Method of measurement

Gastrointestinal symptom rating scale

Secondary outcomes

1

Description

drug complication

Timepoint

intervention period and after treatment

Method of measurement

questioner

Intervention groups

1

Description

Intervention group: Nardostachys jatamansi DC capsules, 400 mg after each meal (TDS) T for one month.

Category

Treatment - Drugs

2

Description

control grope:Domperidone capsules,10 mgr after each meal(TDS)T for one month.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Gastroenterology Clinic

Full name of responsible person

Dr.Javad Shokri Shirvani

Street address

Floor 3 ,Pasargad building,Keshvari st.,khesvari sq.,Bavol,Mazandaran

City

Babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology of Babol University of Medical Sciences

Full name of responsible person

Aliakbar Moghadamni

Street address

Babol Univercity Of Medical Sciences,Ganjafroz st.,Keshvari Sq.,Babol,Mazandaran

City

Babol

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research and Technology of Babol University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Faculty of Traditional Medicine, BabolUivercity Of Medical Sciences

Full name of responsible person

Morteza Mojahedi

Position

Assistant professor of traditional medicin

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty