Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

Comparison of the effects of herbal capsule SOE HAZEMEH (Govarcin) and Metoclopramide on the quality of life in patients with functional dyspepsia

Protocol summary

Study aim
Comparison of the effect of traditional medicine SOE HAZEMEH (Govarcin) and metoclopramide on severity of functional dyspepsia symptoms

Design
A randomized, controlled, double-blind clinical trial with 60 samples, Comparison of two types of drug

Settings and conduct
Patients who refer to the dyspepsia clinic that meet the study entry criteria will be selected by the researcher, then explain the study details, Then, a questionnaire including demographic data and disease information is compiled and Patients were randomly assigned to one of two treatment groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria:Patients 14 to 65 years ;Abnormality of upper gastrointestinal endoscopic results; abdominal ultrasound Not taking Anti-depressant drugs;Not allergic to metoclopramide.;Participation in the study Exclusion criteria:Gastrointestinal ulcer or gastroesophageal reflux disease and Irritable Bowel Syndrome Gastrointestinal;narcotic use; Diabetics; Gastrointestinal; cancers;Pregnant or;lactating women;use of non-steroidal anti-inflammatory drugs;Use of central nervous system weakening drugs;Patient non-cooperation

Intervention groups
Intervention group: SOE HAZEMEH (Govarcin) herbal capsules containing Nigella sativa,Satureja hortensis,Thymus vulgaris, Trachyspermum copticum, Plantago major, Rosa damascena,Pistacia vera; Half an hour before each meal; oral use. Control group:This group is treated with metoclopramide 10 mg. Dosage: Half an hour before each meal as a pill.

Main outcome variables
Upper abdominal pain; Nausea; Vomiting; Heartburn; Quality of Life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190806044456N1**
Registration date: **2019-12-08, 1398/09/17**
Registration timing: **registered_while_recruiting**

Last update: **2019-12-08, 1398/09/17**
Update count: **0**

Registration date
2019-12-08, 1398/09/17

Registrant information

Name
Ahmad Hormati

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 25 3612 2058

Email address
hormatia113@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-09-23, 1398/07/01

Expected recruitment end date
2020-04-20, 1399/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effects of herbal capsule SOE HAZEMEH (Govarcin) and Metoclopramide on the quality of life in patients with functional dyspepsia

Public title
Comparison of the effects of herbal capsule Govarcin and Metoclopramide on Treatment of functional dyspepsia

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients 14 to 65 years of age with any of the symptoms of functional dyspepsia normality of upper gastrointestinal endoscopic results normal abdominal ultrasound Satisfaction with research collaboration

Exclusion criteria:
Taking antipsychotic drugs Use of antidepressants Sensitivity to Metoclopramide

Age
From **14 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, 60 patients with functional dyspepsia will be randomly divided into two groups. The way to select groups is that they will be assigned to groups based on block randomization. Blocks of size 4 are considered. So we will have six blocks containing AABB, ABAB, BBAA, BABA, ABBA, BAAB. Each block will also be randomly selected using a dice throw. For example, if thrown dice is 3, the BBAA block is considered, and therefore the first two patients are assigned to treatment B and the next two patients to treatment A. The dice will be thrown ten times to complete the assignment of patients to the treatment groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
SOE HAZEMEH (Govarcin) is poured into the shell in powder form. Metoclopramide tablets are also poured into the shell and filled with inert filler. The two drugs are packaged in the same form.The differentiation of each drug is a number extracted from the randomization list and provided to the executor as codes A and B.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Qom University of Medical Sciences

Street address
No. 83, No. 4 Alley, 1/1 Alley, Saffashahr street

City
Qom

Province
Ghoum

Postal code
3713649373

Approval date
2019-07-30, 1398/05/08

Ethics committee reference number
IR.MUQ.REC.1398.064

Health conditions studied

1

Description of health condition studied
dyspepsia

ICD-10 code
K30

ICD-10 code description
Functional dyspepsia

Primary outcomes

1

Description
Postprandial fullness

Timepoint
Before taking the drug and 4 weeks after starting medication

Method of measurement
ROM III questionnaire

2

Description
Early Satiety

Timepoint
Before taking the drug and 4 weeks after starting medication

Method of measurement
ROM III questionnaire

3

Description
Abdominal pain
Timepoint
Before taking the drug and 4 weeks after starting medication
Method of measurement
Determination of epigastric pain according to VAS criteria and questionnaire ROM III

4

Description
heartburn
Timepoint
Before taking the drug and 4 weeks after starting medication
Method of measurement
ROM III questionnaire

5

Description
Quality of Life
Timepoint
Before taking the drug and 4 weeks after starting medication
Method of measurement
ROM III questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group consisted of vegetable indigestion capsule (Govarcin). This capsule contains Nigella sativa (20%), Satureja hortensis(10%), Thymus vulgaris(20%), Trachyspermum copticum(20%), Plantago major(10%), Rosa damascena (10%), Pistacia vera(10%).Dosage: Half an hour before a meal. The duration of use of this drug is four weeks. This drug is made by pharmaceutical company Booali Daroo. Its weight is 725 mg.
Category
Treatment - Drugs

2

Description
Control group: The control group consisted of metoclopramide 10 mg. Dosage: Half an hour before each meal is a single dose. It takes four weeks. This tablet is made by Oswah Pharmaceutical Company. It is a tablet that is placed in the capsule and add Microcrystalline cellulose to blind the study.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti hospital
Full name of responsible person
Ahmad Hormati
Street address
Qom University of Medical Sciences and Health Services, Shahid Lavasani street
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Sponsors / Funding sources

1

Sponsor
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Ghoum University of Medical Sciences
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
BooaliDaro Pharmaceutical company
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Ghoum University of Medical Sciences
Full name of responsible person
Ahmad Hormati
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
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Person responsible for updating data

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