

# 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

Ghous

##### 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

##### **City**

Qom

##### **Province**

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##### **Postal code**

3713649373

##### **Phone**

+98 25 3612 2058

##### **Email**

hormatia113@gmail.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Ghous University of Medical Sciences

##### **Full name of responsible person**

Ahmad Hormati

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Qom University of Medical Sciences and Health Services, Shahid Lavasani street

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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**

Ghous 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 scientific inquiries

### Contact

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**Latest degree**

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## Person responsible for updating data

### Contact

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**Full name of responsible person**

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**Latest degree**

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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