

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluating the effect of Gabapentin in improving symptoms of functional dyspeptic patients resistant to routine treatments

#### Protocol summary

##### Study aim

Determination of the effect of oral gabapentin on the improvement of symptoms in patients with functional dyspepsia resistant to conventional treatments

##### Design

In this study, 126 patients with dyspepsia with inclusion criteria are divided into two groups. control and intervention group, the control group receive only the routine treatment, 20 mg of omeprazole daily plus placebo per day, and the intervention group receive in addition to routine drugs, 20 mg omeprazole, 300 mg of gabapentin twice daily. after four weeks the therapeutic effects of the capsule of gabapantine will be examined.

##### Settings and conduct

Clinical trial; Gastrointestinal clinic; placebo-controlled

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Confirmation of functional dyspepsia diagnosis based on Roman criteria Exclusion criteria: Sensitivity to gabapentin, Serious side effect of gabapentin

##### Intervention groups

Intervention group: receive one capsule of 300 mg for 3 nights and then 300 mg twice a day

##### Main outcome variables

Diarrhea, constipation, indigestion, abdominal pain, nausea

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120709010222N19**

Registration date: **2018-09-18, 1397/06/27**

Registration timing: **prospective**

Last update: **2018-09-18, 1397/06/27**

Update count: **0**

##### Registration date

2018-09-18, 1397/06/27

##### Registrant information

###### Name

Zahra Keivani

###### Name of organization / entity

Shahrekord University Of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 38 1222 0016

###### Email address

keivani@skums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-09-23, 1397/07/01

##### Expected recruitment end date

2019-03-21, 1398/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluating the effect of Gabapentin in improving symptoms of functional dyspeptic patients resistant to routine treatments

##### Public title

Evaluating the effect of Gabapentin in improving symptoms of functional dyspeptic patients resistant to routine treatments

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

Confirmation of functional dyspepsia diagnosis

**Exclusion criteria:**

Sensitivity to gabapentin, Serious side effect of gabapentin

**Age**

From **40 years** old to **60 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator

**Sample size**

Target sample size: **126**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Stratified Random Sampling

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The researcher and the patient will have no information about the content of the capsules

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Shahrekord University of Medical Sciences

**Street address**

Kashani street, Shahrekord University of Medical Sciences, Shahrekord

**City**

Shahrekord

**Province**

Chahar-Mahal-va-Bakhtiari

**Postal code**

88187187

**Approval date**

2017-07-01, 1396/04/10

**Ethics committee reference number**

IR.SKUMS.REC.1396.8

**Health conditions studied****1****Description of health condition studied**

Dyspepsia

**ICD-10 code**

K30

**ICD-10 code description**

Functional dyspepsia

**Primary outcomes****1****Description**

Gastrointestinal symptoms

**Timepoint**

Four weeks later

**Method of measurement**

questionnaire

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group:In addition to 20 mg omeprazole,receive 300 mg of gabapentin is given twice a day

**Category**

Treatment - Drugs

**2****Description**

Control group: only receive routine treatment, that is, daily 20 mg of omeprazole plus placebo

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

بیمارستان کاشانی

**Full name of responsible person**

محمدهادی شفیق

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Parastar street, Kashani Hospital of Shahrekord University of Medical Sciences, shahrekord

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Shahre-kord University of Medical Sciences

**Full name of responsible person**

Dr. Kamal Solati

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Kashani street, Shahrekord University of Medical Sciences, Shahrekord

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salati@skums.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Shahre-kord 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**

Shahre-kord University of Medical Sciences

**Full name of responsible person**

Mohammadhadi Shafigh

**Position**

Assistant professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Internal Medicine

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Total data in article format

**When the data will become available and for how long**

2018

**To whom data/document is available**

researcher

**Under which criteria data/document could be used**

article

**From where data/document is obtainable**

journals

**What processes are involved for a request to access data/document**

publication of article

**Comments**