

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

Street address

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

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8818718796

Phone

+98 38 3222 0016

Email

Mhshafigh@skums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Dr. Kamal Solati

Street address

Kashani street, Shahrekord University of Medical Sciences, Shahrekord

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8818618695

Phone

+98 38 3334 2414

Email

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

Street address

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

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8818718796

Phone

+98 38 3222 0016

Email

Mhshafigh@skums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Mohammadhadi Shafigh

Position

استادیار

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

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

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8818718786

Phone

+98 38 3222 0016

Email

Mhshafigh@skums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Mhammadhadi Shafigh

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

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

City

shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8818618696

Phone

+98 38 3222 0016

Email

Mhshafigh@skums.ac.ir

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