

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

comparison of the effect of buccal buspirone administration with placebo in improvement of clinical symptoms in GERD patients

Protocol summary

Study aim

The aim of present study is to determine whether adding buccal buspirone tablet as adjuvant to GERD treatment regimen in patients with GERD will improve the clinical symptoms.

Design

Design of the study is a triple-blind, placebo-controlled, randomized control single center clinical trial. Patients with age more than 15 years old with GERD will be enrolled the study. Patients whom are not desired to enroll the study will be excluded. In this research, 58 eligible patients with GERD compatible with inclusion criteria were chosen. patients were randomly divided into two control and intervention groups by Microsoft Excel software. and a code was allocated to each one of them.

Settings and conduct

This study is conducted as placebo controlled triple blinded randomized clinical trial in taleqani hospital participants, researcher & statistical data analyzer all has been blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: GERD Age more than 15 years old
Exclusion criteria: History of confirmed hypersensitivity reaction to buspirone or omeprazol or any parts of formulation eGFR less than 10 ml/min/1.73m² Liver failure (child pugh C) Pregnancy & lactation concurrent use of MAOI/ conivaptane, tolvaptane/ thalidomide/ dapoxetine

Intervention groups

Intervention group (buccal buspirone): GERD patients compatible with inclusion/exclusion criteria administrated with 10mg buccal buspirone and 20 mg capsul omeprazol daily for 1 months. Control group (buccal buspirone placebo): GERD patients compatible with inclusion/exclusion criteria administrated with 10mg buccal buspirone placebo and 20 mg capsul omeprazol daily for 1 months

Main outcome variables

improvement of clinical symptoms of GERD disease (chest pain/ dyspepsia/ regurgitation / heart burn) 1 months after initiation of buccal buspirone and omeprazole capsule

General information

Reason for update

Acronym

empty

IRCT registration information

IRCT registration number: **IRCT20121021011192N7**

Registration date: **2019-01-10, 1397/10/20**

Registration timing: **registered_while_recruiting**

Last update: **2019-01-10, 1397/10/20**

Update count: **0**

Registration date

2019-01-10, 1397/10/20

Registrant information

Name

Mohammad Abbasinazari

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8887 3704

Email address

m_abbasi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-22, 1397/07/30

Expected recruitment end date

2019-02-19, 1397/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of the effect of buccal buspirone administration with placebo in improvement of clinical symptoms in GERD patients

Public title

buccal buspirone in GERD patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

GERD disease in patients with more than 15 years old

Exclusion criteria:

History of confirmed hypersensitivity reaction to buspirone or omeprazol or any parts of formulation of buccal buspirone eGFR less than 10 ml/min/1.73m² Liver failure (child pugh C) Pregnancy & lactation Concurrent use of thalidomide/ dapoxetine/MAOI/ conivaptane , tolvaptane/

Age

From **15 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **58**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple individual randomization with Microsoft Excel software

Blinding (investigator's opinion)

Triple blinded

Blinding description

Participants, principle investigator, healthcare providers (Physicians, nurses) who care for participants during the trial, data collectors and outcome assessors all are blinded by providing placebo buccal buspirone in same size, shape color, odor and package with real buccal buspirone which organized just by one responsible co-researcher has no involvement in running study

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee school of pharmacy and nursing and midwifery- shahid Beheshti university of medical

Street address

School of Pharmacy, Nyayesh junction, Valiasr street, Tehran

City

Tehran

Province

Tehran

Postal code

1985717413

Approval date

2018-10-08, 1397/07/16

Ethics committee reference number

IR.SBMU.ENDOCRINE.REC.1397.129

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

GERD

ICD-10 code

K21.9

ICD-10 code description

Gastro-esophageal reflux disease without esophagitis

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

improvement of clinical symptoms of GERD (chest pain / regurgitation / dyspepsia/heart burn)

Timepoint

Before intervention and 30 days after initiation of daily use of buccal buspirone and capsule omeprazole

Method of measurement

Interview with patients based on FSSG questionnaire and quality of life questionnaire

Secondary outcomes**1****Description**

Record of Adverse drug reactions

Timepoint

During intervention

Method of measurement

Interview with patients

Intervention groups

1

Description

Intervention group: Addition of buspirone buccal tablet 10 mg/d to omeprazol capsule 20 mg/ d for treatment of GERD for 1 month

Category

Treatment - Drugs

2

Description

Control group: Addition of buspirone placebo buccal tablet 10 mg/d to omeprazol capsule 20 mg/ d for treatment of GERD for 1 month

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Talighani hospital

Full name of responsible person

Mohammad Abbasinazari

Street address

Valiasr street, nyayesh junction, School of pharmacy

City

Tehran

Province

Tehran

Postal code

1996835113

Phone

+98 21 8887 3704

Email

m_abbasi@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Nima Naderi

Street address

School of Pharmacy, Nyayesh junction, Valiasr street,

City

Tehran

Province

Tehran

Postal code

1996835113

Phone

+98 21 8820 9625

Email

naderi@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

zahra sargashteh

Position

board certified clinical pharmacist

Latest degree

Subspecialist

Other areas of specialty/work

Medical Pharmacy

Street address

School of Pharmacy, Nyayesh junction, Valiasr street, Tehran

City

Tehran

Province

Tehran

Postal code

1996835113

Phone

+98 21 4044 8274

Email

zahra.sargashteh@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mohammad Abbasinazari

Position

clinical pharmacy specialist

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

Street address

School of Pharmacy, Nyayesh junction, Valiasr street

City

Tehran

Province

Tehran

Postal code

1996835113

Phone

+98 21 8887 3704

Email

m_abbasi@sbmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

zahra sargashteh

Position

board certified clinical pharmacist

Latest degree

Subspecialist

Other areas of specialty/work

Medical Pharmacy

Street address

School of Pharmacy, Nyayesh junction, Valiasr street

City

Tehran

Province

Tehran

Postal code

1996835113

Phone

+98 21 4044 8274

Email

zahra.sargashteh@gmail.com

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