Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 than10 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 for1 mouths. Control group (buccal buspirone placebo): GERD patients compatible with inclusion/exclusion criteria administrated with 10mg buccal buspirone placebo and 20 mg capsul omeprazol daily for1 mouths

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

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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
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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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Position
board certified clinical pharmacist
Latest degree
Subspecialist
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Person responsible for updating data

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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