Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

A Comparison between lansoprazole with placebo and lansoprazole with duloxetine regimens on symptom and quality of life improvement in patients with Gastroesophageal reflux diseases

Protocol summary

Study aim

Comparison of the effect of lansoprazole with and without duloxetine on the improvement of symptoms and quality of life in patients with gastroesophageal reflux disease.

Design

In a double-blind, randomized, double-blind clinical trial, patients with refractory symptoms that have not received treatment before, referral to Rasool Akram Hospital in year 96, will be included. The criteria for entering the study included people over 18 years of age with typical symptoms of reflux or endoscopic diagnosis of reflux referring to Rasul Akram Hospital, 1995. Exit criteria include recent and previous use of non-steroidal anti-depressant drugs and anxiety or anti-inflammatory drugs, Previous use of proton pump inhibitors, history of allergy to any of the used drugs, etiology of reflux symptoms, previous or recent history of anxiety or severe depression, history of opium and alcohol consumption, history of systemic diseases (heart disease, pulmonary disease, Kidney failure, cancer, myopathy, scleroderma, etc.), previous history of AS Malignant Gastrointestinal Surgery, Previous history of gastric ulcer or duodenum in endoscopy, obese, pregnant. For patients after GERD final diagnosis, two scoring bell questionnaires are used to assess anxiety and depression and in the absence of severe anxiety and depression, the questionnaire of reflux symptoms is filled up. Then, using a randomized table, the numbers are divided into two groups, so that a group Lansoprazole (30 mg / day) plus placebo and the second group of lansoprazole (30 mg / day) with duloxetine (30 mg / day) for up to four weeks. After the end of the treatment period, the symptoms are again based on each questionnaire Previous treatments are evaluated and compared between the two groups. It should be noted that the placebo is prepared by the pharmaceutical company

Settings and conduct

This is a single blind(participants and care provider) randomized clinical trial.All patients with typical symptoms of gastroesophageal re flux disease with age between 18-65 years ,and without exclusion criteria,who referred to Rasoul-e-Akram hospital , randomly assigned in one of the treatment groups.Each group consist of 27 patients.

Participants/Inclusion and exclusion criteria

Inclusion criteria:patients with typical symptom and/or endoscopic findings of gastroesophageal re flux disease with age between 18-65 years. Exclusion criteria:history of anti-depressant and/or-anxiety and non steroid anti-inflammatory drugs;any allergy history to prescribed drugs;atypical reflux symptome;severe depression or anxiety;opium or alcohol user;history of systemic disease(cardiac,pulmonary,renal,liver diseaseand myopathy,sclerodermia and cancer);upper gastrointestinal surgery;any history of peptic ulcer disease;morbid obesity;pregnancy

Intervention groups

Group A:Capsule lansoprazole 30 milligram plus capsule placebo daily Group B:Capsule lansoprazole 30 milligram plus capsule duloxetine30 milligram daily

Main outcome variables

Typical symptoms ;quality of life of patients with gastroesophageal re flux disease

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141201020178N6**
Registration date: **2018-02-04, 1396/11/15**
Registration timing: **registered_while_recruiting**

Last update: **2018-02-04, 1396/11/15**

Update count: **0**

Registration date

2018-02-04, 1396/11/15

Registrant information

Name

Marjan Mokhtare

Name of organization / entity

Iran University of Medical sciences,Rasoul Akram Hospital,Colorectal Research Center

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-03, 1396/09/12

Expected recruitment end date

2018-06-20, 1397/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparison between lansoprazole with placebo and lansoprazole with duloxetine regimens on symptom and quality of life improvement in patients with Gastroesophageal reflux diseases

Public title

The effect of Duloxetine with lansoprazole on the treatment of Gastroesophageal reflux disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

age between 18-65 Typical symptoms of Gastro - esophageal reflux disease (heartburn, regurgitation)and/ or endoscopic findings of Gastroesophageal reflux disease

Exclusion criteria:

Use of recent or previous anti-depressants and anti-anxiety drugs A history of allergy to any of the medications History of alcohol consumption Atypical symptoms of Gastro esophageal reflux disease Previous history of anxiety or depression History of opium use History of upper gastrointestinal disorders(Dyspepsia and/or Peptic ulcer disease) History of cardiac , pulmonary , musculoskeletal disease and any malignancy. History of medications such as: Sildenafil, calcium channel blocker, methylxanthine, nitrate and beta-agonist Age under 18 years Age older than sixty-five

Age

From **18 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: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

Computerized random Table

Blinding (investigator's opinion)

Double blinded

Blinding description

After explanation for patients about the study, and getting written concent form ,all the enrolled patients are blindly randomized to each group. Outcome assessors dont informed about the type of regimens in this study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Iran University of Medical Sciences

Street address

West Shahid Hemmat Highway,Intersection of Chamran and Sheikh Fazlollah Noori

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2017-12-03, 1396/09/12

Ethics committee reference number

IR.IUMS.FMD.REC1396.9311160007

Health conditions studied

1

Description of health condition studied
gastroesophageal reflux
ICD-10 code
K21
ICD-10 code description
Gastro-esophageal reflux disease

Primary outcomes

1

Description
Quality and symptoms of patients with gastroesophageal reflux Disease
Timepoint
Before starting the intervention and 4 weeks later
Method of measurement
Patient Assessment of gastroesophageal re flux Quality of life and symptom Questionnaires

Secondary outcomes

1

Description
Adverse effect of medications
Timepoint
2 and 4 weeks after starting the intervention
Method of measurement
Data gathering sheet of patients

Intervention groups

1

Description
Intervention group: Tablet Lansoprazole 30 mg daily with Capsule Duloxetine 30 mg daily(Abidi company)
Category
Treatment - Drugs

2

Description
Control group: Tablet Lansoprazole 30 mg daily with Capsule placebo daily(Abidi company)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Colorectal Research Center,Rasoul Akram Hospital
Full name of responsible person
Marjan Mokhtare
Street address
Sattarkhan Street,Niayesh Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
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Seyed Kazem Malakooti
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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
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Marjan Mokhtare
Position
Assistant Professor
Latest degree
Subspecialist

Other areas of specialty/work
Gastroenterology and Hepatology
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Title and more details about the data/document
IPD collected for primary outcome could be shared
When the data will become available and for how long
starting in September 2018
To whom data/document is available
People working in academic institutions
Under which criteria data/document could be used
Just analyzed data
From where data/document is obtainable
Email address Research Administrator of Colorectal Research Center, Marjan Mokhtare
What processes are involved for a request to access data/document
After applying for analyzed data by email, we review it and answer them
Comments