Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jul 2026

Comparison of the effect of duloxetine with nortriptyline on depression, anxiety, and quality of life in patients with functional dyspepsia

Protocol summary

Study aim
Comparing the effect of duloxetine with nortriptyline on depression, anxiety, and quality of life in patients with functional dyspepsia

Design
46 patients are initially evaluated by the desired questionnaires. Then, based on the table of random numbers, they are placed in one of groups A (Duloxetine) or B (Nortriptyline). They are re-evaluated after three months. The test work is in phase 4

Settings and conduct
Patients referred to the GI clinic of Taleghani Hospital are included in the study. At the beginning ,it is measured using Nepin's quality of life questionnaire and Hamilton's depression and anxiety questionnaires. Group A volunteers are treated with duloxetine at a dose of 20 to 30 mg daily for 3 months, and group B receives 10 to 20 mg nortriptyline daily. Score of quality of life, anxiety and depression based on Nepin and Hamilton questionnaires at the end of the first month, the end of the second month, and the end of the third month after the start of the survey by an interviewer who does not know which medicine the patient is taking received, are evaluated.

Participants/Inclusion and exclusion criteria
inclusion criteria: age 18 -70 years, education diploma, willingness to cooperate in the project, and not having an allergy to duloxetine and nortriptyline. Exclusion criteria: suffering from any type of serious psychiatric illness or other gastrointestinal disease, taking antidepressants or antipsychotic drugs in the last 6 weeks, not fully answering the questionnaires, not cooperating in the follow-ups, causing severe side effects of the drug used. pregnancy or breastfeeding, desire to leave the project

Intervention groups
Patients with functional dyspepsia are divided into two groups. Duloxetine will be prescribed for the first group and nortriptyline for the second group.

Main outcome variables
Improving the level of anxiety, depression, quality of life and disease symptoms

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220329054367N2**
Registration date: **2022-11-06, 1401/08/15**
Registration timing: **registered_while_recruiting**

Last update: **2022-11-06, 1401/08/15**
Update count: **0**

Registration date
2022-11-06, 1401/08/15

Registrant information

Name
Seyed Shahab Banihashem

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 2243 2540

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-09-23, 1401/07/01

Expected recruitment end date
2023-09-23, 1402/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Comparison of the effect of duloxetine with nortriptyline on depression, anxiety, and quality of life in patients with functional dyspepsia

Public title
Comparison of the effect of psychiatric drugs on the improvement of psychological symptoms and disease severity in patients with functional dyspepsia

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
All patients with functional dyspepsia based on ROME-IV Having a diploma education Willingness to cooperate in the project Not having an allergy to Deloxetine and Nortriptyline

Exclusion criteria:
Having any type of serious psychiatric illness (severe anxiety or depression, psychosis, bipolar disorder, anorexia or bulimia nervosa) Having any other gastrointestinal disease except functional dyspepsia Taking antidepressants or antipsychotics in the last 6 weeks Failure to complete the questionnaires Non-cooperation in follow-ups causing severe side effects of the drug used (Deloxetine or Nortriptyline) Pregnancy or breastfeeding during the study period

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
4

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **46**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be assigned to two arms, using block randomization method. The block size is four, involving 3 patients (based on order’s coming) which would generated by online block randomization software “Sealed Envelope”. The list of random blocks will be placed in envelopes, daily would be opened by the staffs.

Blinding (investigator's opinion)
Single blinded

Blinding description
Patients are evaluated at the end of the first month, the end of the second month and the end of the third month after the start of the examination by an interviewer who does not know which medicine the patient received.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address
Velenjak

City
Tehran

Province
Tehran

Postal code
1985717443

Approval date
2021-07-14, 1400/04/23

Ethics committee reference number
IR.SBMU.MSP.REC.1400.176

Health conditions studied

1

Description of health condition studied
functional dyspepsia

ICD-10 code
K30

ICD-10 code description
Functional dyspepsia

Primary outcomes

1

Description
anxiety

Timepoint
Measuring anxiety before the start of the study and one, two and three months after the start of the intervention

Method of measurement
Hamilton anxiety questionnaire

2

Description
depression

Timepoint
Measuring depression before the start of the study and one, two and three months after the start of the intervention

Method of measurement
Hamilton depression questionnaire

3

Description

quality of life

Timepoint

Measuring quality of life before the start of the study and one, two and three months after the start of the intervention

Method of measurement

Nippen questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the first intervention group, 20 mg duloxetine (Cymbalta brand name) is prescribed for patients. Patients are advised to take the medicine with food. Patients should take this medicine for three months.

Category

Treatment - Drugs

2

Description

Intervention group: In the first intervention group, nortritiline drug with a dose of 25 mg (Aventyl brand name) is prescribed for the patients. Patients are advised to take the medicine with food. Patients should take this medicine for three months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani hospital

Full name of responsible person

Amir Sadeghi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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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

Full name of responsible person

Mahsa Mofateolshia

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Confidentiality of participants' data

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
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
The study protocol, statistical analysis map and study report will be available to those who request more information about the plan

When the data will become available and for how long
Since the publication of the article

To whom data/document is available
Researchers, research companies, students, professors

Under which criteria data/document could be used
In order to complete the information of a study and citing the reference

From where data/document is obtainable
To the authors of the project

What processes are involved for a request to access data/document
Sending a request email to the responsible author and mentioning the reason for the request and how to use the information

Comments