

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)

Phone

+98 21 2243 2540

Email address

shb_banihashem@sbm.ac.ir

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		Secondary Ids	empty
Scientific title	Comparison of the effect of duloxetine with nortriptyline on depression, anxiety, and quality of life in patients with functional dyspepsia	Ethics committees	
Public title	Comparison of the effect of psychiatric drugs on the improvement of psychological symptoms and disease severity in patients with functional dyspepsia	1	
Purpose	Treatment	Ethics committee	
Inclusion/Exclusion criteria		Name of ethics committee	Ethics Committee of Shahid Beheshti University of Medical Sciences
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	Street address	Velenjak
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	City	Tehran
Age	From 18 years old to 70 years old	Province	Tehran
Gender	Both	Postal code	1985717443
Phase	4	Approval date	2021-07-14, 1400/04/23
Groups that have been masked	- Outcome assessor - Data analyser	Ethics committee reference number	IR.SBMU.MSP.REC.1400.176
Sample size	Target sample size: 46	Health conditions studied	
Randomization (investigator's opinion)	Randomized	1	
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.	Description of health condition studied	functional dyspepsia
Blinding (investigator's opinion)	Single blinded	ICD-10 code	K30
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.	ICD-10 code description	Functional dyspepsia
Placebo	Not used	Primary outcomes	
Assignment	Parallel	1	
Other design features		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

Street address
Velenjak

City
Tehran

Province
Tehran

Postal code
1985711151

Phone
+98 21 2243 2540

Email
taleghanihospital@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Alireza Zali

Street address
Velenjak

City
Tehran

Province
Tehran

Postal code
1985717443

Phone
+98 21 2243 2525

Email
info@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
Mahsa Mofateolshia

Position
Resident

Latest degree
Specialist

Other areas of specialty/work
Psychiatrics

Street address
Velenjak

City
Tehran

Province
Tehran

Postal code
1985717443

Phone
+98 21 2243 2541

Email
mahsa.3652@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Shahab Banihashen

Position

assistant professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

Velenjak

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 2243 2524

Email

shb_banihashem@sbmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Somayeh Motazedian

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

Velenjak

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

009812243241

Email

somayehmotazedian@yahoo.com

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