Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effects of Escitalopram and Doxepin on improving anxiety and depression and quality of life in patients with chronic obstructive pulmonary disease (COPD)

Protocol summary

Study aim

Determining and comparing the rate of depression, anxiety and quality of life before and after taking Doxepin and Escitalopram and placebo and comparing symptoms with the severity of chronic obstructive pulmonary disease (COPD).

Design

Two-blind clinical trial on 72 patients, randomized into two intervention groups and one placebo group

Settings and conduct

Vali-e-Asr Hospital, Internal ward and Clinic, 72 patients are randomly divided into two intervention groups and one placebo group، To blind the drugs, they are packaged and prepared in the form of uniform capsules by the supervisor, who provides them to the researcher. The researcher and the Data collector under study are both blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: having any class of COPD with any severity, having symptoms of depression and anxiety. Exclusion criteria: patients with any underlying disease other than chronic obstructive pulmonary disease and depression and anxiety, patients who have recently (two weeks from the start of the study)Have taken monoamine oxidase inhibitors or those taking these medications.

Intervention groups

The intervention group includes patients with chronic obstructive pulmonary disease receiving doxepin (25 mg/day) and citalopram (10 mg/day). And the control group from the same patients who receive placebo capsules daily

Main outcome variables

anxiety and depression and quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161023030452N2**
Registration date: **2021-06-04, 1400/03/14**
Registration timing: **registered_while_recruiting**

Last update: **2021-06-04, 1400/03/14**
Update count: **0**

Registration date

2021-06-04, 1400/03/14

Registrant information

Name

Seyed abolfazl Ghoreishi

Name of organization / entity

Zanjan university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 24 3342 0651

Email address

sabgho@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-10, 1400/02/20

Expected recruitment end date

2021-06-18, 1400/03/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effects of Escitalopram and Doxepin on improving anxiety and depression and quality of life in patients with chronic obstructive pulmonary disease (COPD)

Public title

Evaluation of the effects of citalopram and doxepin in patients with chronic obstructive pulmonary disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 40 years Having any class of COPD with any severity Having symptoms of depression and anxiety Patients with stable COPD so that their disease status does not change from day to day and are under constant treatment and there is no change in the type of treatment

Exclusion criteria:

Those whose illness has worsened recently (one week from the start of the study) or while studying Patients with severe dementia, severe cognitive impairment, end-stage cancer, and mental illness, including schizophrenia, suicidal ideation, and more Patients who have recently (two weeks after the start of the study) taken monoamine oxidase inhibitors or those who are taking these medications Patients whose ECG shows long QT intervals Pregnant or lactating women Patients with severe liver, kidney, cardiovascular and motor diseases Patients with uncontrollable epilepsy Patients with a history of intolerance to antidepressants

Age

From **40 years** old

Gender

Both

Phase

3

Groups that have been masked

- Investigator
- Outcome assessor

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

In the present study, block randomization will be used to assign to study groups. In this method, blocks of 6 sizes are created, then enough blocks are selected to reach the required sample size in each group. Individual randomization unit is a random number table randomization tool. This type of random assignment will cause the ratio in each of the studied groups to be almost equal at any time of the research. As it is known, 12 blocks of 6 will be created and finally, 24 samples will be placed in 3 groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

In In this study, the researcher and data collector did not know which drugs or placebo were. Only the main person in charge of the study (the supervisor) knows about the drug or placebo, and due to the fact that the form of the drugs is different, before starting the study, all the drugs are packaged in the same capsules by the supervisor and Provides to the researcher (resident).

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Committee of Ethics, Zanjan University of Medical Sciences

Street address

Zanjan University of Medical Sciences, Azadi Square, Zanjan

City

Zanjan

Province

Zanjan

Postal code

4515613191

Approval date

2020-12-15, 1399/09/25

Ethics committee reference number

IR.ZUMS.REC.1399.332

Health conditions studied

1

Description of health condition studied

Depression

ICD-10 code

F32.8

ICD-10 code description

Other depressive episodes

2

Description of health condition studied

Anxiety

ICD-10 code

F06.4

ICD-10 code description

Anxiety disorder due to known physiological condition

3

Description of health condition studied

Chronic obstructive pulmonary disease

ICD-10 code

J44

ICD-10 code description

Other chronic obstructive pulmonary disease

Primary outcomes

1

Description

Depression score in the questionnaire

Timepoint

Depression at the beginning of the study (before the intervention) 14 days 30 days and 60 days after the intervention

Method of measurement

DASS 21 Questionnaire

2

Description

Anxiety score in the questionnaire

Timepoint

Anxiety at the beginning of the study (before the intervention) 14 days 30 days and 60 days after the intervention

Method of measurement

DASS 21 Questionnaire

3

Description

Stress score in the questionnaire

Timepoint

Stress at the beginning of the study (before the intervention) 14 days 30 days and 60 days after the intervention

Method of measurement

DASS 21 Questionnaire

4

Description

Physical health score in the questionnaire

Timepoint

Physical health score at the beginning of the study (before the intervention) 14 days 30 days and 60 days after the intervention

Method of measurement

WHOQOL-BREF questionnaire

5

Description

Mental health score in the questionnaire

Timepoint

Mental health score at the beginning of the study (before the intervention) 14 days 30 days and 60 days after the intervention

Method of measurement

WHOQOL-BREF questionnaire

6

Description

Social relations score in the questionnaire

Timepoint

Social relations score at the beginning of the study (before the intervention) 14 days 30 days and 60 days after the intervention

Method of measurement

WHOQOL-BREF questionnaire

7

Description

Environmental health score

Timepoint

Environmental health score at the beginning of the study (before the intervention) 14 days 30 days and 60 days after the intervention

Method of measurement

WHOQOL-BREF questionnaire

8

Description

General health score (quality of life)

Timepoint

General health score (quality of life) at the beginning of the study (before the intervention) 14 days 30 days and 60 days after the intervention

Method of measurement

WHOQOL-BREF questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Doxepin 25 mg of the tricyclic antidepressant drug is given as a capsule from Sobhan Pharmaceutical Company once a day for two months to 24 patients with chronic obstructive pulmonary disease.

Category

Treatment - Drugs

2

Description

Intervention group: Escitalopram 10 mg of antidepressant drug serotonin reuptake inhibitors is given as a capsule from Sobhan Pharmaceutical Company once a day for two months to 24 patients with chronic obstructive pulmonary disease.

Category

Treatment - Drugs

3

Description

Intervention group: The ready-made placebo is given as a capsule from Sobhan Pharmaceutical Company once a day for two months to 24 patients with chronic obstructive pulmonary disease.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Zanjan University of Medical Sciences Valiasr Hospital

Full name of responsible person

Dr.S.A. Ghoreishi

Street address

Ark Str, Shahid Beheshti Hospital, Zanjan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan 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

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Dr.S.A. Ghoreishi

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Position

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Latest degree

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Position

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Latest degree

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

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

Yes - There is 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

No - There is not a plan to make this available

Title and more details about the data/document

All data is potentially shareable after unidentified individuals

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Medical students and doctors working in private centers

From where data/document is obtainable

Shahid Dr Beheshti Hospital, Zanjan University of Medical Sciences. Dr Seyed Abolfazl Goreishi sabgho@zums.ac.ir

What processes are involved for a request to access data/document

After sending the email after review within a week sabgho@zums.ac.ir

Comments