Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effectiveness of duloxetine and nortriptyline in the treatment of pain in rheumatoid arthritis patients

Protocol summary

Study aim
Considering that antidepressants have an effect on the improvement of patients' pain and can also have an effect on the quality of life, so the purpose of this study is to compare the effectiveness of Duloxetine and Nortriptyline to in treating the pain in Rheumatoid Arthritis patients.

Design
Clinical trial, with parallel groups, phase 3, double blind, randomized on 54 patients, randomization by Permuted Block Randomization

Settings and conduct
Rheumatoid arthritis patients who visited the rheumatology clinic of Imam Hossein (AS) hospital in 1401 and 1402 and complained of pain were randomly assigned to two groups receiving Duloxetine and Nortriptyline. The study will be conducted in a double-blind manner so that both the patients and the prescribing physician will be completely unaware of the nature of the prescribed medication and how the groups will be randomized. Patients in each group will receive the drug for 3 months. The intensity of pain before the intervention and after one, two and three months of the intervention will be measured with a Visual Analogue Scale.

Participants/Inclusion and exclusion criteria
Age over 18 years; Clinical diagnosis of Rheumatoid Arthritis; Presence of Anti CCP or RF in serum; patients treated with Methotrexate, Hydroxychloroquine, and Prednisolone; articular involvement without extra-articular involvement; complaints of pain; absence of pregnancy and breastfeeding; absence of major psychiatric illness; age less than 70 years; absence of allergy to Nortriptyline and Duloxetine

Intervention groups
After selection, based on the inclusion and exclusion criterias, the patients will be placed in two groups of consumer of Nortriptyline or Duloxetine for 3 months.

Main outcome variables
Pain level based on Visual Analogue Scale

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220901055848N1**
Registration date: **2023-02-18, 1401/11/29**
Registration timing: **registered_while_recruiting**

Last update: **2023-02-18, 1401/11/29**
Update count: **0**

Registration date
2023-02-18, 1401/11/29

Registrant information

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Fateme Kazemi Khaledi

Name of organization / entity

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-02-09, 1401/11/20

Expected recruitment end date
2024-02-09, 1402/11/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Comparison of the effectiveness of duloxetine and nortriptyline in the treatment of pain in rheumatoid arthritis patients

Public title
Comparison of the effectiveness of duloxetine and nortriptyline in the treatment of pain in rheumatoid arthritis patients

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Confirmation of the clinical diagnosis of mild to moderate Rheumatoid Arthritis by a rheumatologist Presence of RF or AntiCCP in the serum of patients Patients under treatment with methotrexate, prednisolone and hydroxychloroquine Articular involvement without extra-articular involvement Age range from 18 to 70 years Pain complaint Consent to participate in the study

Exclusion criteria:
The presence of major psychiatric disorders, including depression, anxiety disorders, bipolar, schizophrenia, abuse of any substance and medication. History of allergy to Duloxetine or Nortriptyline Pregnancy, breastfeeding, or planning to become pregnant in the near future Refusing to consent to receive treatment according to the instructions of this protocol

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **54**

Randomization (investigator's opinion)
Randomized

Randomization description
The 4 random blocks are used. Each label has a letter A or B and the random sequence method is created using the website www.sealedenvelope.com using the random block method of 4 based on treatment group A or B for 54 (two groups of 27) patients. Block randomization works by randomizing participants into blocks, so that equal numbers are assigned to each treatment. For example, given a block size of 4, there are 6 possible ways to equally assign participants to a block.

Blinding (investigator's opinion)
Double blinded

Blinding description
Nortriptyline and Duloxetine drugs with similar packaging, with different codes from the combination of numbers and letters A and B are used. Each patient is assigned a code at the beginning of the study, which is known by that code until the end of the study. Both the patients and the prescribing doctor are unaware of the patient grouping.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee of Shahid Beheshti University of Medical Sciences (Faculty of Medicine)

Street address
Shahid Madani Street

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Tehran

Province
Tehran

Postal code
1617763141

Approval date
2022-12-24, 1401/10/03

Ethics committee reference number
IR.SBMU.MSP.REC.1401.482

Health conditions studied

1

Description of health condition studied
pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Pain level

Timepoint
Pain measurement before, 1 month, 2 months and 3 months after the start of taking one of the two drugs Nortriptyline and Duloxetine

Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: will be treated with Nortriptyline 10 mg of Abidi company on a daily basis; which is based on the clinical response of pain reduction (which is based on previous clinical trials a reduction of more than 30% in the baseline VAS score) for patients who did not achieve a clinical response in subsequent visits up to the maximum daily dose of 150 mg will be considered. The treatment will be done for 3 months. In order to follow up, patients will be visited 1 month, 2 months and 3 months later. And pain intensity will be measured using VAS in each of these visits.

Category
Treatment - Drugs

2

Description
Intervention group 2: will be treated with Duloxetine 20 mg of Abidi company on a daily basis; which is based on the clinical response of pain reduction (which is based on previous clinical trials a reduction of more than 30% in the baseline VAS score) for patients who did not achieve a clinical response in subsequent visits up to the maximum daily dose of 120 mg will be considered. The treatment will be done for 3 months. In order to follow up, patients will be visited 1 month, 2 months and 3 months later. And pain intensity will be measured using VAS in each of these visits.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Hossein Hospital

Full name of responsible person
Roya Vaziri Harami

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Roya Vaziri Harami

Position
Assisstant professor

Latest degree
Specialist

Other areas of specialty/work
Psychiatrics

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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
Yes - There is a plan to make this available

Title and more details about the data/document
All data is potentially shareable after de-aidentifying individuals.

When the data will become available and for how long
The access period starts 6 months after the results are published

To whom data/document is available
All researchers working in academic and scientific institutions, doctors and pharmaceutical companies will be allowed to access the information.

Under which criteria data/document could be used
The applicant can access the information after providing proof of identity

From where data/document is obtainable
The applicant can contact Dr. Fateme Kazemi Khaledi via e-mail: fatemekazemikhaledi@gmail.com to receive the desired documents or data.

What processes are involved for a request to access data/document
The applicant can communicate with the researcher through e-mail and receive the basic data after presenting the identity documents.

Comments