Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

comparison of the effect of Saffron and Duloxetine on pain and depression in Rheumatoid arthritis

Protocol summary

Study aim

comparison of the effect of Saffron and Duloxetine on pain and depression in Rheumatoid arthritis

Design

this is a double-blind clinical trial with placebo control.participants were selected from patients referring to the rheumatology clinic of imam Ali hospital in Zahedan who are treated with an RA diagnosis and have criteria for entering the study and if have the criteria of exit study removed from the list of volunteers. the sample size is 75 people who will be randomly assigned to 3 groups of 25 people.

Settings and conduct

groups will include the Duloxetine , saffron capsule and the placebo receptors.to reduce errors , the capsules of 3 groups are completely similar in appearance and the therapist and volunteer are not aware of its contents. at first , the volunteers undergo VAS test for pain and patient with a score over 40 will be included in the study. BPI and hamilton tests for depression are performed for all patients and the scores are recorded.

Participants/Inclusion and exclusion criteria

inclusion criteria: ACR criteria for RA pain intensity at least 40 according to VAS the age is equal to or greater than 18 years exclusion criteria: current or previous treatment with doluxetine axis I psychological disorder except MDD pain caused by traumatic injery other structural rheumatologic disorder except RA regional rheumatic diseases(osteoarthritis - bursitis - tendonitis) multiple sclerosis history of repeated surgery inflammatory , infectious , autoimmune arthritis serious medical illneses(untreated endocrine diseases - liver diseases - cardiovascular diseases - AIDS - seizure - malignancy) pregnancy - lactation - non proper use of contraception simultaneous use of psychiatric drugs(MAOIS , Serotonergic drugs) active suicidal thoughts abuse of alcohol or drugs over the past 2 years use of muscle relaxants , steroid , opioid analgesics , BZDs , anticonvulsants in a recent week injection of analgesic at painful point in a recent month use of thioridazine and other drugs affect on Cytochrome P450 in two recent weeks

Intervention groups

the Duloxetine group will receive 30 mg capsules in the first week and then 60 mg will be given in two divided doses. the saffron group will be received 15 mg capsules daily in the first week and then twice daily. the placebo group will be received one capsule daily in the first week and then twice daily. for volunteers in the weeks 0,1,3 and 6 , BPI and Hamilton tests will be performed and their scores will be recorded and in addition to the tests , side effects and exclusion criteria will be reviewed. at intervals of weeks the tests CBC , LFT , FBS and electrolytes will be performed to monitor the side effects of the drugs. the duration of the drug in this study is considered to be 6 weeks. finally the variables considered are statistically tested and the result will be interpreted. groups will be identical in terms of age and gender.

Main outcome variables

reduce pain and depression in rheumatoid arthritis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171106037265N1**
Registration date: **2018-03-07, 1396/12/16**
Registration timing: **registered_while_recruiting**

Last update: **2018-03-07, 1396/12/16**
Update count: **0**

Registration date

2018-03-07, 1396/12/16

Registrant information

Name

Name of organization / entity

Country
Iran (Islamic Republic of)
Phone
+98 912 541 2100
Email address
a.fardi@zaums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2017-12-21, 1396/09/30
Expected recruitment end date
2018-04-20, 1397/01/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
comparison of the effect of Saffron and Duloxetine on pain and depression in Rheumatoid arthritis

Public title
comparison of the effect of Saffron and Duloxetine on pain and depression in Rheumatoid arthritis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
ACR criteria for RA pain intensity at least 40 according to VAS
Exclusion criteria:
current or previous treatment with duloxetin axis I psychological disorder except MDD other structural rheumatological disorder except RA inflammatory , infectious , autoimmune arthritis active suicidal thoughts
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **75**
Randomization (investigator's opinion)
Randomized
Randomization description
easy to use and available from examples that are included the terms of entry, and assigning samples to either group is based on blocked grouping.
Blinding (investigator's opinion)
Double blinded
Blinding description
the sample size calculated for this study is 75 people that they will randomly be grouped into 25 people.groups will include the Duloxetine , saffron capsule and the placebo receptors.to reduce errors , the capsules of 3 groups are completely similar in appearance and the therapist and volunteer are not aware of its contents.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committe of Zahedan University of Medical Sciences
Street address
DrHesabi Square
City
zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Approval date
2017-09-23, 1396/07/01
Ethics committee reference number
IR.ZAUMS.REC.1396.158

Health conditions studied

1

Description of health condition studied
Depression
ICD-10 code
F32.0
ICD-10 code description
Major depressive disorder, single episode, mild

2

Description of health condition studied
Depression
ICD-10 code
F32.1
ICD-10 code description
Major depressive disorder, single episode, moderate

Primary outcomes

1

Description
pain in Rheumatoid arthritis
Timepoint
first, third, sixth weeks
Method of measurement
BPI Questionnaire

2

Description
depression in Rheumatoid arthritis
Timepoint
first, third, sixth weeks
Method of measurement
Hamilton Depression Survey Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: the Duloxetine group will receive 30 mg capsules(Sobhan pharmaceutical company) in the first week and then 60 mg will be given in two divided doses.the duration of the drug in this study is considered to be 6 weeks.
Category
Treatment - Drugs

2

Description
Control group:the placebo group will be received one capsule daily in the first week and then twice daily(construction of pharmacy under the contract of Zahedan university of medical sciences). the duration of the drug in this study is considered to be 6 weeks.
Category
Placebo

3

Description
Intervention group: the saffron group will be received 15 mg capsules (Daroopakhsh pharmaceutical company) daily in the first week and then twice daily. the duration of the drug in this study is considered to be 6 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ali-Ebn-Abitaleb hospital
Full name of responsible person
Akbar Fardi
Street address
Khalijfars Blvd
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Noormohammad Bakhshani
Street address
DrHesabi Square
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akbarfardi58@gmail.com
Grant name
Thesis cost
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zahedan 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
Zahedan University of Medical Sciences

Full name of responsible person
Akbar Fardi

Position
psychiatric assistant

Latest degree
Medical doctor

Other areas of specialty/work
Psychiatrics

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Zahedan, DrHesabi square

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Person responsible for scientific inquiries

Contact

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Akbar Fardi

Position
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Latest degree
Medical doctor

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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