Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jun 2026

Comparing The Analgesic Effect Of Agomelatin Versus Placebo In Combination With Pregabalin In Patients With Chronic Low Back Pain : A Randomized , Double-Blinded Study

Protocol summary

Study aim

Evaluating the effectiveness of Agomelatin in chronic low back pain and the effectiveness in disabilty nad depression caused by chronic low back pain

Design

The patients aged between 18 to 60 after complete description and taking the informed consent will enter this study and with the usage of randomization and Balanced Block RAndomization , they will divide into 2 groups(first group taking Pregabalin75 mg BD + Placebo Daily and the second group taking Pregabalin 75mg BD + Agomelatin25mg daily) Before taking Agomelatin and in the third week of its usage the liver enzymes will be checked.They will be evauated in 0 , 1,4,8 week .the 1st week will be by phone.in the 4th and 8th week they will answer the questionnaire .The lab data will be checkd in 4th week.

Settings and conduct

Rasoul akram Hospital

Participants/Inclusion and exclusion criteria

Patients with chronic low back pain without an indication for surgery.Chronic low back pain+patients with low back pain for at least 3 months(almost everyday) Patients aged between 18 to 60

Intervention groups

Intervention group : taking pregabalin + agomelatin
Control group : taking pregabalin + placebo

Main outcome variables

severity of pain before and after taking Pregabalin ; Severity of pain before and after taking agomelatin ; severity of disability before and after taking Pregabalin ; Severity of pain before and after taking Agomelatin ; Severity of depression and anxiety before and after taking Agomelatin ; Severity of pain before and after taking Pregabalin; severity of depression and anxiety before and after taking pregabalin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200620047852N1**
Registration date: **2020-06-23, 1399/04/03**
Registration timing: **prospective**

Last update: **2020-06-23, 1399/04/03**
Update count: **0**

Registration date

2020-06-23, 1399/04/03

Registrant information

Name

Shayan Amiri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2236 3375

Email address

amiri.shayan23@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-06, 1399/04/16

Expected recruitment end date

2020-10-07, 1399/07/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparing The Analgesic Effect Of Agomelatin Versus Placebo In Combination With Pregabalin In Patients With Chronic Low Back Pain : A Randomized , Double-Blinded Study

Public title
"Agomelatin in chronic low back pain"

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with chronic low back pain without an indication for surgery.Chronic low back pain+patients with low back pain for at least 3 months(almost everyday) Patients aged between 18 to 60

Exclusion criteria:
Patiens with long term usage of Opioids , Anti depressants , Benzodiazepines,Gabaergic drugs Any contraindications for using each drugs(Agomelatin or Pregabalin) Liver enzymes three times more than normal Patients with depression disorder or suicidal thoughts or psychosis or acute manic phase or cognitive disorder or anxiety disorder or PTSD who needs treatment. These patients will exclude by an interview done by an educated psycholoy resident due to DSM5 Patients who need surgery will exclude PAtients who are taling any Anti-depressants drugs Patients who took Pregabalin within 1 month Patients who are taking physiotherapy courses will exclude Life expectancy under 12 month Patients who are pregnant or during breastfeeding period

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **84**

Randomization (investigator's opinion)
Randomized

Randomization description
Clinical trial with control groups , parallel group , double-blinded, randomized with placebo(random allocation).In this study we will use Balance Block Randomization.In order to concealment happends , the tables of the groups and the drugs boxes(which includes 2types:the first one is Pregabalin with Placebo and the second one is Pregabalin with Agomelatin)will held by someone except the analyzer or interviewer.Neither the analyzer nor the interviewer do not know about the groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
In order to concealment happends , the tables of the groups and the drugs boxes(which includes 2types:the first one is Pregabalin with Placebo and the second one is Pregabalin with Agomelatin)will held by someone except the analyzer or interviewer.Neither the analyzer nor the interviewer do not know about the groups.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Iran university of medical sciences

Street address
No 24- First west street -24 metres boulvard-saadat abad-tehran - iran

City
Tehran

Province
Tehran

Postal code
۱۹۹۸۶۶۷۱۳۳

Approval date
2020-06-17, 1399/03/28

Ethics committee reference number
IR.IUMS.FMD.REC.1399.200

Health conditions studied

1

Description of health condition studied
Chronic low back pain

ICD-10 code
M54.5

ICD-10 code description
Low back pain

Primary outcomes

1

Description
Score of pain in brief pain inventory scale (BPI) questionnaire

Timepoint
The beginning of the the study and 1st,4th,8th week

Method of measurement
Brief pain inventory scale (BPI) questionnaire

Secondary outcomes

1

Description
Roland-Morris Disability Questionnaire (RMDQ)
Timepoint
The beginning of the study and 1st,4th,8th week
Method of measurement
Roland-Morris Disability Questionnaire (RMDQ)

2

Description
Score of anxiety and depression by The Hospital Anxiety and Depression Scale (HADS)
Timepoint
The beginning of the study and 1st,4th,8th week
Method of measurement
Roland-Morris Disability Questionnaire (RMDQ)

3

Description
Evaluating the health and function of the patients using SF-36 questionnaire
Timepoint
The beginning of the study and 1st,4th,8th week
Method of measurement
SF-36 questionnaire

4

Description
Evaluating the psychologic status of the patients using GHQ-28 questionnaire
Timepoint
The beginning of the study and 1st,4th,8th week
Method of measurement
GHQ-28 questionnaire

5

Description
Evaluating the demographic variables using the questionnaire designed by the researcher
Timepoint
The beginning of the study and 1st,4th,8th week
Method of measurement
Questionnaire designed by researcher

6

Description
Evaluating the drugs complications by drug checklist designed by researcher
Timepoint
The beginning of the study and 1st,4th,8th week
Method of measurement
drug check list designed by the researcher

Intervention groups

1

Description
Intervention group: we will prescribe Pregabalin 75mg BD + Agomelatin25mg once a day.Before starting Agomelatin and in the 3rd week we will check Liver enzymes. PATIENTS WILL BE EVALUATED IN 0,1,4,8 weeks.in the 1st week the evaluation will be by phone. In the other week the evaluation Will be In clinic.In the 4th week we will Complete the questionnaire and check the Lab data.in the 0,8 week the questionnaire will be completed again too.All the drugs and Laboratory tests and Visit by doktors will be gratitude for the participants.
Category
Treatment - Drugs

2

Description
Control group: we prescribe Pregabalin75mg BD + Placebo once a day. PATIENTS WILL BE EVALUATED IN 0,1,4,8 weeks.in the 1st week the evaluation will be by phone. In the other week the evaluation Will be In clinic.In the 4th week we will Complete the questionnaire and check the Lab data.in the 0,8 week the questionnaire will be completed again too.All the drugs and Laboratory tests and Visit by doktors will be gratitude for the participants.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasoul Akram Hospital
Full name of responsible person
Shayan Amiri
Street address
Rasoul Akram Hospital-Niayesh street - Sattarkhan
City
Tehran
Province
Tehran
Postal code
۱۹۹۸۶۶۴۵۳
Phone
+98 21 6435 2342
Email
amiri.shayan@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Seyyed Abas Motevalian

Street address
Iran university of medical science-shahid hemmat highway
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 86701
Email
adminsite@iums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Shayan Amiri
Position
Orthopaedic surgery resident
Latest degree
Medical doctor
Other areas of specialty/work
Orthopedics
Street address
No24, First West Street, 24 metres boulvard,saadat abad,tehran , iran
City
Tehran
Province
Tehran
Postal code
1998667133
Phone
+98 21 2236 3375
Fax
Email
Amiri.shayan23@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Shayan Amiri
Position
Orthopaedic surgery resident
Latest degree
Medical doctor
Other areas of specialty/work
Orthopedics
Street address
No24, First West Street, 24 metres boulvard,saadat abad,tehran , iran
City
Tehran
Province
Tehran
Postal code
1998667133
Phone
+98 21 2236 3375
Fax
Email
Amiri.shayan23@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Shayan Amiri
Position
Orthopaedic surgery resident
Latest degree
Medical doctor
Other areas of specialty/work
Orthopedics
Street address
No24, First West Street, 24 metres boulvard,saadat abad,tehran , iran
City
Tehran
Province
Tehran
Postal code
1998667133
Phone
+98 21 2236 3375
Fax
Email
Amiri.shayan23@gmail.com

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

Participant data research's protocol Statistical analysis map Informed consent form Clinical research report Analysis's codes Data's dictionary All the datas will be available after making them unknown in order to keep the secrets of the participants.

When the data will become available and for how long

All data will be available after publishing the results

To whom data/document is available

everybody

Under which criteria data/document could be used

it is allowed to do any analysis or researchs with citation.

From where data/document is obtainable

the main researcher - dr shayan amiri by e-mail. amiri.shayan@gmail.com

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

After receiving e-mail , i will send all the requested information within 1 week

Comments