

# 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 disability and 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 Pregabalin 75 mg BD + Placebo Daily and the second group taking Pregabalin 75mg BD + Agomelatin 25mg daily) Before taking Agomelatin and in the third week of its usage the liver enzymes will be checked. They will be evaluated 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 checked 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:

Patients 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 happens , 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 happens , 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 boulevard-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 + Agomelatin 25mg 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 doctors will be gratitude for the participants.

### **Category**

Treatment - Drugs

## 2

### **Description**

Control group: we prescribe Pregabalin 75mg 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 doctors 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**

admins@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 boulevard,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**

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**Person responsible for updating data****Contact****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

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**Position**

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**Latest degree**

Medical doctor

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+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**