

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Studying the therapeutic effects of Methylprednisolone Acetate and lidocaine injection at GB-20 acupuncture point compared to oral Duloxetine in patients with Fibromyalgia

Protocol summary

Study aim

Studying the therapeutic effects of injection of methylprednisolone acetate and lidocaine in gallbladder-20 (GB-20)acupuncture point in reducing pain of patients with Fibromyalgia

Design

Clinical trial in phase 3 with 2 parallel groups randomized with block randomization method(with same block length) on 30 patients.

Settings and conduct

visiting fibromyalgia patients will take place in clinic of rajaee hospital of shiraz city. after filling out the informed consent form and fibromyalgia impact questionnaire and visual analog scale one of the methylprednisolone injection or oral duloxetine will be given to the patient .on follow up 2,4,8 weeks later all the questionnaires will be filled again .

Participants/Inclusion and exclusion criteria

inclusion criteria:1-diffuse body pain in different body parts both side of the body during the last week.2-problems like weakness-after sleep fatigue-Impaired thought and memory.3-abdominal pain ,depression and headache in the last 6 mouths exclusion criteria:1-patinets who have Diabetes- thyroid dysfunction- Neuropathy-Lyme disease-hepatitis C.2-patient with uncontrolled psychiatrics disease 3.individuals who use medications which have drug interaction with duloxetine

Intervention groups

Intervention group :patient with fibromyalgia who will receive methylprednisolone and lidocaine injection at GB-20 accupoint. control group :patient with fibromyalgia who will receive oral duloxetine.

Main outcome variables

Body pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210308050630N1**

Registration date: **2021-06-10, 1400/03/20**

Registration timing: **registered_while_recruiting**

Last update: **2021-06-10, 1400/03/20**

Update count: **0**

Registration date

2021-06-10, 1400/03/20

Registrant information

Name

Navid Ahmadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3230 9473

Email address

dr.navidahmadi.pmr@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-09, 1399/12/19

Expected recruitment end date

2021-08-22, 1400/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Studying the therapeutic effects of Methylprednisolone Acetate and lidoaine injection at GB-20 acupuncture point compared to oral Duloxetine in patients with Fibromyalgia

Public title

Studying therapeutic effects of Methylprednisolone Acetate and Lidocaine injection in patients with Fibromyalgia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

patient diagnosed with fibromyalgia base on American College of Rheumatology guideline. Completing and signing the consciout consent form Abdominal pain, depression and headache for the last 6 mounths. pain in dfferent parts of body like Neck-Jaw-Shoulder-upper Arm-lower Arm-Chest-Abdomen-Back-upper Thigh at both sides of the body for the last week problems like weakness ,after sleep fatigue, impaired thought and memory for the last week

Exclusion criteria:

Patients with Diabetes mellitus-Thyroid disease-Neuropathy-Lyme disease-Hepatitis patients who use medications like ASA-Metoclopramide-Tamoxiphen-TCA-alfa agonists-Beta cyprotrone uncontrolled mental illness

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, block randomization method is used. Blocking is usually used to balance the number of samples assigned to each of the study groups. The size of all blocks is equal and, in this study, we will have blocks with size of 4, including 2 patient in the duloxetine group and 2 patient in the methyl group. Randomization is done by computer using Random allocation software version 1.0.0. For concealment, we use random allocation concealment using opaque sealed and sequentially numbered envelopes, so that the assigned group is not known before the individual is assigned. In this method, each of the random sequences created is recorded on a card and the cards are placed in the envelopes in order. In order to maintain the random sequence, the envelopes are numbered in the same way on the outer surface. Finally, the envelopes are glued and placed in a box, respectively. Based on the order of entry of eligible patients into the study, one of the envelopes is opened in order and their assigned group is revealed

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

Street address

No.11,Ansar Ave,Koohbar Blvd,Zerehi

City

Shiraz

Province

Fars

Postal code

7184747811

Approval date

2020-10-26, 1399/08/05

Ethics committee reference number

IR.SUMS.MED.REC.1399.330

Health conditions studied**1****Description of health condition studied**

Fibromyalgia

ICD-10 code

M79.7

ICD-10 code description

Fibromyalgia

Primary outcomes**1****Description**

body pain

Timepoint

Before treatment-2-4-8 weeks later

Method of measurement

Visual Analogue Scale

Secondary outcomes**1****Description**

functional status

Timepoint

Before treatment -2-4-8 weeks after treatment

Method of measurement

FIBROMYALGIA IMPACT QUESTIONNAIRE (FIQ)

Intervention groups

1

Description

Intervention group: for this group only once injection of the mixture of Methylprednisolone acetate and Lidocaine 2% will be performed ,to each GB-20 accupoint ,each side 3 cc with needle gauge 23-(Methylprednisolone acetate is from Iran Hormon Pharmaceutical and Lidocaine is from Caspian Tamin Pharmaceutical)

Category

Treatment - Drugs

2

Description

Control group:for this group Duloxetine cap 30 mg is given once daily which after 1 week it will be two times daily.duloxetine is a drug from SNRI group which has FDA approval for treatment of firomyalgia.the medication well be given for 8 weeks. duloxetine is from Abidi pharmaceutical.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Rehabilitation Clinic

Full name of responsible person

Mani Ramzi

Street address

Namazi Square

City

Shiraz

Province

Fars

Postal code

714737-71348

Phone

+98 71 7000 3212

Email

motahari@sums.ac.ir

2

Recruitment center

Name of recruitment center

Rajae Hospital

Full name of responsible person

Amir Reza Mesbahi

Street address

Chamran Blvd

City

Shiraz

Province

Fars

Postal code

71944815711

Phone

+98 71 4001 3636

Email

Ragaeehospital@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Ghasemi

Street address

خیابان ملاصدرا-خیابان خلیلی -روبروی آموزشگاه معارف

City

Shiraz

Province

Fars

Postal code

7134814336

Phone

+98 71 3628 1506

Email

info@sums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Navid Ahmadi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

Street address

No.4 abaeeyan street,abaeeyan,zand street

City

Shiraz

Province

Fars

Postal code

۷۱۳۴۸-66676

Phone

+98 71 3230 9473

Email

dr.navidahmadi.pmr@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Navid Ahmadi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

Street address

No.4Abaeeyan street,Abaeeyan street,Zand street

City

Shiraz

Province

Fars

Postal code

71348-66676

Phone

+98 71 3230 9473

Email

dr.navidahmadi.pmr@gmail.com

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

Shiraz University of Medical Sciences

Full name of responsible person

Navid Ahmadi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

Street address

No.4 abaeeyan street,abaeeyan street,Zand street

City

Shiraz

Province

Fars

Postal code

71348-66676

Phone

+98 71 3230 9473

Email

dr.navidahmadi.pmr@gamil.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

all available data can be shared after making people unidentifiable.

When the data will become available and for how long

access period starts one year after publishing the results

To whom data/document is available

Every one can have access to this information

Under which criteria data/document could be used

If the information in this study improves the scientific process.

From where data/document is obtainable

dr.navidahmadi.pmr@gmail.com 00989122415918

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

after sending the desired message ,all authors of this study will be consulted if permitted ,all information will be sent within 3 weeks maximum.

Comments