Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

Studying the therapeutic effects of Methylprednisolone Acetate and lidoaine 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 conscious 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 uncontroled 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
Rajaee Hospital
Full name of responsible person
Amir Reza Mesbahi
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Chamran Blvd
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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 اموزشگاه معارف
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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
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Person responsible for updating data

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Latest degree
Medical doctor
Other areas of specialty/work
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City
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Fars
Postal code
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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 publiushing 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