

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

The effect of acupuncture supplement on the pain of patients with acute low back pain referring to the emergency department

Protocol summary

Study aim

The effect of acupuncture on the pain of patients with acute low back pain referring to the emergency department.

Design

Two arm parallel group randomized trial and outcome assessment

Settings and conduct

In this study, patients with patient satisfaction before randomization in this way, patients from studying Emam Reza Hospital of Mashhad Emergency Hospital are selected by sampling if they have entry requirements and personal satisfaction. The selection of individuals to the intervention and control group will be randomized with the help of numbers in sealed envelopes. In this case, envelopes will be provided to the number of participants and arranged in each group with the help of random numbers in each envelope. To be With the arrival of patients, the relevant envelope is opened and the patient group is identified. Patients are divided into two equal groups of NSAID recipients who are taking ibuprofen 600 mg four times a day for two weeks and another being treated with ankle-acupuncture with ibuprofen.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 25 to 55 years old Exclusion criteria: pregnancy With trauma Disability Acute low back pain with red flags: history of cancer, risk factors of cancer, abnormal Physical nerve examination, Evidence of infection such as fever, Intravenous drug users, Recent bacterial infection, Immunodeficiency, Embedding the inside of the spinal Lower back pain for more than six weeks Contraindication to receive NSAIDs

Intervention groups

The control group consisted of forty patients who receive the usual drug treatment. The intervention group 2 consists of forty patients who receive interventional acupuncture supplementation.

Main outcome variables

The pain rate of patients at the moment of entry and two hours later and the next day after acupuncture. Patient pain rate at the time of entry and two weeks after ibuprofen treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190521043662N1**

Registration date: **2019-06-24, 1398/04/03**

Registration timing: **retrospective**

Last update: **2019-06-24, 1398/04/03**

Update count: **0**

Registration date

2019-06-24, 1398/04/03

Registrant information

Name

Payman Delavar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3821 6646

Email address

delavarp941@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-10, 1396/10/20

Expected recruitment end date

2019-02-06, 1397/11/17

Actual recruitment start date

2018-01-10, 1396/10/20

Actual recruitment end date

2019-02-06, 1397/11/17

Trial completion date

2019-04-15, 1398/01/26

Scientific title

The effect of acupuncture supplement on the pain of patients with acute low back pain referring to the emergency department

Public title

Effect of acupuncture in low back pain

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

The patients with acute low back pain referring to the emergency department

Exclusion criteria:

Age less than 25 Age over 55

Age

From **25 years** old to **55 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **80**

Actual sample size reached: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Allocation to the intervention and control group by the random allocation method with help of numbers in sealed envelopes. acupuncture in a group is added to the standard treatment of a specified dose of ibuprofen.

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 Mashhad University of Medical Sciences

Street address

Namaz 11

City

Mashhad

Province

Razavi Khorasan

Postal code

917 735 6993

Approval date

2018-02-28, 1396/12/09

Ethics committee reference number

ارسال شده است admin که به ایمیل 1396.784.rec.fm.mums.ir

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

Acute low back pain

ICD-10 code

M00-M99

ICD-10 code description

بیماری‌های سیستم اسکلتی عضلانی و بافت همبند

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

Pain score

Timepoint

The moment of arrival (zero hour) and two hours later (2 hours) and the day (24 hours) after acupuncture in forty patients and Patient pain at the time of entry and two weeks after treatment with ibuprofen in forty patients.

Method of measurement

Numeric rating scale questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: The effect of an ankle acupuncture treatment Comes with Ibuprofen.

Category

Treatment - Other

2**Description**

Control group: Ibuprofen drug recipients

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center**

Name of recruitment center

Imam reza hospital
Full name of responsible person
Payman.Delavar
Street address
Namaz 11
City
Mashhad
Province
Razavi Khorasan
Postal code
917 735 6993
Phone
+98 51 3821 6646
Email
Paydelavar@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Ehsab.Bolverdi
Street address
Saberı Blvd, Imam reza hospital
City
Mashhad
Province
Razavi Khorasan
Postal code
917 735 6993
Phone
+98 51 3852 5312
Fax
+98 51 3852 5312
Email
Bolvardie@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences
Full name of responsible person
Bolvardi.Ehsan
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Emergency Medicine
Street address
Saberı Blvd, Imam reza hospital
City
Mashhad
Province
Razavi Khorasan
Postal code
917 735 6993
Phone
+98 51 3852 5313
Fax
+98 51 3852 5312
Email
Bolvardie@muns.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Bolvardi.Ehsan
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Emergency Medicine
Street address
Saberı Blvd, Imam reza hospital, edalatian emergency
City
Mashhad
Province
Razavi Khorasan
Postal code
917 735 6993
Phone
+98 51 3821 6646
Fax
+98 51 3852 5312
Email
Bolvardie@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Bolvardi.Ehsan
Position
Professor

Latest degree

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Emergency Medicine

Street address

Saberi Blvd, Imam reza hospital, edalatian emergency

City

Mashhad

Province

Razavi Khorasan

Postal code

917 735 6993

Phone

+98 51 3852 5313

Fax

+98 51 3852 5312

Email

Bolvardie@mums.ac.ir

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