Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Compare the clinical efficacy of oral gabapentin and naproxen on the severity of bone and joint pain in brucellosis patients admitted in Imam Hossein hospitals of Shahroud on 2016-2017

Protocol summary

Study aim

Compare the clinical efficacy of oral gabapentin and naproxen on the severity of bone and joint pain in brucellosis patients

Design

In this research, 86 eligible patients referring to Imam Hossein Hospitalwere chosen purposefully and a code was allocated to each one of them. Then, patients were randomly (Using random quadrants blocks) divided into two control and intervention groups.

Settings and conduct

This study was performed as a randomized clinical trial among patients admitted to Imam Hossein Shahroud Hospital with brucellosis diagnosis.The study is a double blind clinical trial and the participants, the main investigator, the data collectors, and those who evaluate the outcome are blind

Participants/Inclusion and exclusion criteria

Inclusion criteria: Definitive diagnosis of brucellosis There is no history of systemic disease (such as diabetes or thyroid disease), vascular diseases, coagulation problems (eg hemophilia), history of gastrointestinal bleeding and structural disorders (scoliosis and spondylolisthesis, etc.) No neurological symptoms such as SLR and Cross-SLR, decreased tendin reflexes and decreased sensation in examination Age range 15 to 65 years Complaint of severe and Fairly intense bone and joint pain Desire and satisfaction to enter the study Exclusion criteria: Corticosteroid injections in the lumbar region or other areas of the body within 3 months before and during the study Dissatisfaction to continue treatment Those who use drugs A history of back pain or repetitive back pain is more than 4 times a year Taking multiple medications for other illnesses (such as hypnotics, anti-leptic, relaxants) Severe hypersensitivity to any of the two drugs, gabapentin and naproxen Dissatisfaction with cooperation and participation in the project

Intervention groups

Intervention group: 100 mg gabapentin tablets twice daily (200 mg daily) Control group: 250 mg naproxen tablets twice daily (500 mg daily)

Main outcome variables

Intensity of pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171124037609N1**
Registration date: **2018-02-05, 1396/11/16**
Registration timing: **registered_while_recruiting**

Last update: **2018-02-05, 1396/11/16**
Update count: **0**

Registration date

2018-02-05, 1396/11/16

Registrant information

Name

Farnaz Rivjam

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7792 6610

Email address

rewjam@shmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date
2018-09-22, 1397/06/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Compare the clinical efficacy of oral gabapentin and naproxen on the severity of bone and joint pain in brucellosis patients admitted in Imam Hossein hospitals of Shahroud on 2016-2017

Public title
Compare the clinical efficacy of oral gabapentin and naproxen on the severity of bone and joint pain in brucellosis patients
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Definitive diagnosis of brucellosis There is no history of systemic disease (such as diabetes or thyroid disease), vascular diseases, coagulation problems (eg hemophilia), history of gastrointestinal bleeding and structural disorders (scoliosis and spondylolisthesis, etc.) No neurological symptoms such as SLR and Cross-SLR, decreased tendin reflexes and decreased sensation in examination Age range 15 to 65 years Complaint of severe and Fairly intense bone and joint pain Desire and satisfaction to enter the study
Exclusion criteria:
Corticosteroid injections in the lumbar region or other areas of the body within 3 months before and during the study Dissatisfaction to continue treatment Those who use drugs A history of back pain or repetitive back pain is more than 4 times a year Taking multiple medications for other illnesses (such as hypnotics, anti-leptic, relaxants) Severe hypersensitivity to any of the two drugs, gabapentin and naproxen Dissatisfaction with cooperation and participation in the project
Age
From **15 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **86**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization is simple; the randomization unit is individual; the randomization tool of the Envelope is blocked; the method of constructing the random sequence of the quadrilateral block; the allocation concealment is using a blocked envelope, each containing a control or intervention group
Blinding (investigator's opinion)
Double blinded
Blinding description
The study is a double blind clinical trial and the participants, the main investigator, the data collectors, and those who evaluate the outcome are blind
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahroud University of Medical Sciences
Street address
shahroud University of Medical Sciences and Health Services,Hafte-Tir Square,Shahroud
City
shahroud
Province
Semnan
Postal code
۳۶۱۴۷-۷۳۹۴۷
Approval date
2016-07-26, 1395/05/05
Ethics committee reference number
IR.SHMU.REC.1395.72

Health conditions studied

1

Description of health condition studied
Brucellosis
ICD-10 code
A23.9
ICD-10 code description
Brucellosis, unspecified

Primary outcomes

1

Description
Intensity of pain
Timepoint
On the third, fifth and seventh day after the intervention
Method of measurement
Visual Analog Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 100 mg gabapentin tablets twice daily (200 mg daily)
Category
Treatment - Drugs

2

Description
Control group: 250 mg naproxen tablets twice daily (500 mg daily)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahroud Imam Hussein Hospital
Full name of responsible person
Farnaz Rivjam
Street address
Lane 28-meter Ayatollah Tohidi ,Imam Street. Shahrood City
City
Shahroud
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Semnan
Postal code
1648813879
Phone
+98 23 3234 2000
Email
Farnaz_r457@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
Mohammad Hassan Emamian
Street address
shahroud University of Medical Sciences and Health Services,Hafte-Tir Square,Shahroud
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Postal code
۳۶۱۴۷۷۳۹۴۷
Phone
+98 23 3239 5054
Email
emamian@shmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahroud 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
Shahroud University of Medical Sciences
Full name of responsible person
Farnaz Rivjam
Position
medical student
Latest degree
A Level or less
Other areas of specialty/work
General Practitioner
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Shahroud University of Medical Sciences and Health Services, Hafte-Tir Square, Shahroud
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Full name of responsible person

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Position

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Latest degree

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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