

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Comparison the effect of acupressure and relaxation on pain intensity in lower extremity of traumatic patients in pre-hospital emergency care

Protocol summary

Study aim

Comparison of acupressure and Respiratory relaxation on pain intensity

Design

Clinical trial intervention

Settings and conduct

Researcher (A) provides a brief explanation of how the study is performed and receives the patient's verbal consent to participate in the study, and technician A is responsible for performing the interventions. Pain is then measured by the NRS once after placement in the ambulance (immediately before the intervention) and once immediately after the intervention (before leaving the ambulance and being delivered to the treatment center) by Technician B. . If the route is long, the pain intensity measurement will be repeated every 10 minutes. In intervention group 1, routine care + acupressure is performed by wearing a special acupressure bracelet on the P6 point of the wrist for 10 minutes. The second group of routine care intervention + respiratory relaxation is performed by diaphragmatic method in the form of 5 inhales and exhales and 30 seconds of stopping the intervention and repeating in a period of 10 minutes. For each separate part of this technique, the patient inhales and exhales 5 times. Relatively deep and slow (DSB), so that the diaphragm plays a more effective role in breathing. In the third group (control group), only routine care is performed.

Participants/Inclusion and exclusion criteria

All patients aged 15 to 65 years, with trauma to the ankle or ankle with full consciousness and no wounds are the conditions for inclusion in the study.

Intervention groups

Group 1. Press on the p6 point using the wrist strap
Group 2. Perform respiratory relaxation
Group 3 control with receiving routine care

Main outcome variables

Pain condition and vital signs

General information

Reason for update

Acronym

کنترل درد

IRCT registration information

IRCT registration number: **IRCT20191208045659N3**

Registration date: **2021-09-06, 1400/06/15**

Registration timing: **registered_while_recruiting**

Last update: **2021-09-06, 1400/06/15**

Update count: **0**

Registration date

2021-09-06, 1400/06/15

Registrant information

Name

Sefollah Alaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3365 4190

Email address

alaei@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-06, 1400/05/15

Expected recruitment end date

2021-11-06, 1400/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of acupressure and relaxation on pain intensity in lower extremity of traumatic patients in pre-hospital emergency care

Public title

Comparison the effect of acupressure and relaxation on pain intensity

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 15 to 65 years Trauma patients with full consciousness No open wounds Leg or ankle trauma

Exclusion criteria:

Altered level of consciousness or hemodynamic Active bleeding Dissatisfaction with participating in the study

Age

From **15 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Available samples that meet the inclusion criteria will be randomly assigned to one of the control groups, intervention 1 (acupressure) and intervention 2 (relaxation) using the software. Randomization will be done using random list preparation software, so that 30 random 3-block blocks (A-B-C) will be introduced by the software and based on that, qualified samples will be selected and placed in each group. Randomization will be done using online software. Creating a random A Created Blocked Randomization List / Sealed Envelope will be done, so that 30 random 3 blocks (ABC) will be introduced by the software and based on that, qualified samples will be selected and They will be placed in each group.

Blinding (investigator's opinion)

Single blinded

Blinding description

Researcher (A) provides a brief explanation of how the study is performed and receives the patient's verbal consent to participate in the study, and technician A is responsible for performing the interventions. Pain is then measured by the NRS once after placement in the ambulance (immediately before the intervention) and once immediately after the intervention (before leaving the ambulance and being delivered to the treatment center) by Technician B. Meanwhile the person analyzing the collected information is unaware of which of the intervention or control groups the relevant information belongs to.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Research Ethics Committee of Semnan University of Medical Sciences

Street address

Semnan, Basij Blvd., Headquarters of Semnan University of Medical Sciences and Health Services

City

semnan

Province

Semnan

Postal code

3514799442

Approval date

2021-02-23, 1399/12/05

Ethics committee reference number

IR.SEMUMS.REC.1399.319

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

Closed Fractures of leg

ICD-10 code

S82.80

ICD-10 code description

Fractures of other parts of lower leg, closed

2**Description of health condition studied**

Fractures of other parts of lower leg, closed

ICD-10 code

S82

ICD-10 code description

Fractures of other parts of lower leg, closed

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

Reduce the severity of pain

Timepoint

10 minutes after the intervention

Method of measurement

Numerical rating scale

Secondary outcomes

1

Description

Vital Signs

Timepoint

10 minutes after interventions

Method of measurement

Monitoring device

Intervention groups

1

Description

Intervention group: Routine care + acupuncture is done by tying the acupuncture bracelet on the P6 point of the wrist for 10 minutes

Category

Treatment - Devices

2

Description

Intervention group: Routine care + diaphragmatic relaxation is performed in the form of 5 inhalations and exhalations and 30 seconds of stopping intervention and repeating in a period of 10 minutes.

Category

Treatment - Other

3

Description

Control group: Perform routine care

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Pre-hospital emergency service centers

Full name of responsible person

Mohammad Hossein Kamangari

Street address

Babol, Kargar Square - Ganj Afroz St. B University of Medical Sciences - next to the Faculty of Dentistry

City

babol

Province

Mazandaran

Postal code

4717643633

Phone

+98 11 3320 9804

Email

kamangari115@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Asgari

Street address

Semnan niversity of Medical Sciences, km 5 of Damghan road

City

Semnan

Province

Semnan

Postal code

3513138111

Phone

+98 23 3365 4191

Email

sem.ums.nursingmidwifery.res@gmail.com

Grant name

Grant code / Reference number

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

No

Title of funding source

Nursing Care Center of Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Dr. Sefollah Alaei

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Semnan niversity of Medical Sciences, km 5 of Damghan road

City

Semnan

Province

Semnan

Postal code
3513138111
Phone
+98 23 3365 4170
Email
alaei@semums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Dr. Sefollah Alaei
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Semnan niversity of Medical Sciences, km 5 of
Damghan road
City
Semnan
Province
Semnan
Postal code
3513138111
Phone
002333654170-71
Email
alaei@semums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Dr Sefollah Alaei
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Semnan niversity of Medical Sciences, km 5 of
Damghan road
City
Semnan
Province
Semnan
Postal code
3513138111

Phone
009823336171
Email
alaei@semums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Yes. Appropriate non-personal data will be published as an article in the form of data group analysis

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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Data on general characteristics (age, sex, type of injury, pain intensity), research samples, method of work, and findings of interventions will be published in the form of articles in research journals as well as as a student's master's thesis.

When the data will become available and for how long

The period of access to articles in the journal will be related to the policies of the journal. Also, access to the data of research dissertation is depend on the publishing rules of Semnan University of Medical Sciences

To whom data/document is available

Researchers in the field of medical sciences as well as those involved in care and treatment

Under which criteria data/document could be used

To help improve research status as well as patient care

From where data/document is obtainable

Published information is published in journals, to receive the content of the dissertation, to the libraries of Semnan University of Medical Sciences or its sites

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

Its steps are listed on the library site. For information articles in journals, according to the policies of each journal, so it will be determined in the future

Comments

Classification, precise organization and dissemination of information depending on the status of data, the policies of Semnan University of Medical Sciences at the time of the final presentation of the research project and also the selected journal to publish the article will have