Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
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Iran (Islamic Republic of)
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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 + acupressure is done by tying the acupressure 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 Afrooz St. B University of Medical Sciences - next to the Faculty of Dentistry
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Dr. Mohammad Reza Asgari
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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
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Person responsible for updating data

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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