Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 2026

Evaluation of the effect of acupuncture on the pain intensity caused by the insertion of vascular needles in blood donors

Protocol summary

Study aim
Evaluation of the effect of acupuncture on the pain intensity caused by the insertion of vascular needles in blood donors

Design
Clinical trial with parallel control group, double blind, randomized, Control with placebo, single center trial, Sample size 60 blood donors.

Settings and conduct
Kowsar Hospital in Semnan. For all people, metal needles No. 7 for blood sampling (made by Makofarma Iran Company) are used and are inserted into a vein in the front area of the left forearm by a person. The angle of needle entry into the vein is 30-45 degrees and the diagonal edge of the needle is upward as it enters.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Absence of simultaneous pain in another area of the body. Exclusion criteria: Intolerance to pressure in the area of acupressure; Impossibility of taking blood vessel from the person in the first attempt; Existence of injury, lesion, or trauma at the site of acupressure that intervention is not possible.

Intervention groups
Intervention group 1: Five minutes before the blood collection needle is inserted, the LI4 acupressure point of both hands is pressed for 1.5 minutes and repeated after a 10-second pause. The needle is then inserted into a blood vessel in the anterior region of the forearm. (3 times in total and for a total of 5 minutes). Intervention group 2 (Placebo): Five minutes before the needle is inserted, the acupressure intervention is performed outside the LI4 acupressure point of both hands, between the fourth and fifth metacarpals behind the palm. The needle is then inserted into a blood vessel in the anterior region of the forearm. Control group: Only for comparison with intervention group, no intervention is performed.

Main outcome variables
Intensity of pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20151228025732N55**
Registration date: **2020-08-15, 1399/05/25**
Registration timing: **prospective**

Last update: **2020-08-15, 1399/05/25**
Update count: **0**

Registration date
2020-08-15, 1399/05/25

Registrant information

Name
Alireza Emadi

Name of organization / entity
Semnan University of Medical Sciences, Semnan, Iran

Country
Iran (Islamic Republic of)

Phone
+98 23 3345 1336

Email address
are20935@semums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-08-20, 1399/05/30

Expected recruitment end date
2021-08-21, 1400/05/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of acupuncture on the pain intensity caused by the insertion of vascular needles in blood donors

Public title
Evaluation of the effect pain intensity caused by the insertion of vascular needles in blood donors
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:
Absence of simultaneous pain in another area of the body
Exclusion criteria:
Intolerance to pressure in the area of acupressure Impossibility of taking blood vessel from the person in the first attempt Existence of injury, lesion, or trauma at the site of acupressure that intervention is not possible
Age
From **25 years** old to **50 years** old
Gender
Male

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization; Individual; Random Number Tables. Randomized permutation blocks (block 3). Using Excel software to generate random number tables
Blinding (investigator's opinion)
Double blinded
Blinding description
The participant, the main researcher, health personnel who evaluate the outcomes will not be informed about the grouping of patients and the type of medication.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Semnan University of Medical Sciences
Street address
Semnan University of Medical Sciences, Basij Blvd, Semnan
City
Semnan
Province
Semnan
Postal code
3514799442
Approval date
2020-07-28, 1399/05/07
Ethics committee reference number
IR.SEMUMS.REC.1399.131

Health conditions studied

1

Description of health condition studied
Intensity of pain
ICD-10 code
G89
ICD-10 code description
Pain, not elsewhere classified

Primary outcomes

1

Description
Intensity of pain
Timepoint
Before and after inserting a vascular needle
Method of measurement
Numeric Pain Rating Scale (NRPS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: To find the Large intestine 4 (LI4) acupressure point, the Point exell model acupuncture precision point finder is used. Five minutes before the blood collection needle is inserted (Makofarma Iran Company), the LI4 acupressure point of both hands is pressed for 1.5 minutes and repeated after a 10-second pause. The needle is then inserted into a blood vessel in the anterior region of the forearm. (3 times in total and for a total of 5 minutes).
Category
Treatment - Devices

2

Description
Intervention group 2 (Placebo): Five minutes before the needle is inserted, the acupressure intervention is

performed outside the LI4 acupressure point of both hands, between the fourth and fifth metacarpals behind the palm. The needle is then inserted into a blood vessel in the anterior region of the forearm. (3 times in total and for a total of 5 minutes).

Category

Treatment - Devices

3

Description

Control group: Only for comparison with intervention group, no intervention is performed.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Kowsar Hospital

Full name of responsible person

Mohammadreza Asgari

Street address

Street Amin, Semnan

City

Semnan

Province

Semnan

Postal code

3519899951

Phone

+98 23 3345 1336

Email

are20935@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Fatemeh Ehsani

Street address

Semnan University of Medical Sciences, Basij Blvd, Semnan.

City

Semnan

Province

Semnan

Postal code

3514799442

Phone

+98 23 3345 1336

Email

fatemehehsani59@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

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

Mohammadreza Asgari

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Semnan University of Medical Sciences, Basij Blvd, Semnan

City

Semnan

Province

Semnan

Postal code

3514799442

Phone

+98 23 3345 1336

Email

are20935@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Mohammadreza Asgari

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Semnan University of Medical Sciences, Basij Blvd, Semnan

City

Semnan
Province
Semnan
Postal code
3514799442
Phone
+98 23 3345 1336
Email
are20935@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Mahdiesadat Zargar
Position
Student
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
Semnan University of Medical Sciences, Basij Blvd, Semnan
City
Semnan
Province
Semnan
Postal code
3514799442
Phone
+98 23 3345 1336
Email
are20935@gmail.com

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
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available