Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 May 2026

Comparison of cold compress or pressure bandage, in addition to applying continuous local pressure, on the incidence and severity of hematoma and ecchymosis caused by radial artery sampling in the intensive care unit.

Protocol summary

Study aim
Comparative study of three methods of continuous local pressure and applying cold compress and compression bandage on the incidence and severity of hematoma and ecchymosis

Design
A clinical trial with one control group and two intervention groups, parallel and randomized, without blinding, phase 2-3, on 60 volunteers. A simple randomization method is used for randomization.

Settings and conduct
This study, which will be conducted at Namazi Hospital in Shiraz, is not blinded. After the initial evaluation of the inclusion criteria and performing the modified Allen test to ensure adequate blood supply to the distal part of the body, the volunteers will be randomly divided into three groups and receive interventions related to their group. Then, 48 hours after the intervention, the consequences of the occurrence and severity of hematoma and ecchymosis will be investigated and compared.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Informed consent; Allen test; Systolic blood pressure below 180 Exclusion criteria: The presence of diseases of the vessels of the upper limbs; infection, swelling, or ulceration in the radial area; Presence of shunt or graft or fistula in upper limb areas

Intervention groups
In intervention group 1: After applying the routine treatment similar to the control group, a cold compress is used for 3 minutes. In intervention group 2: after applying the same routine treatment as the control group, it is closed using 3 relatively vertical elastic bandages. Control group: Immediately after the needle exit, local pressure is applied with two fingers for 5 minutes using a 4 x 4 piece of gauze, if the bleeding continues, pressure will be applied until the bleeding stops completely.

Main outcome variables
incidence and severity of hematoma, and incidence and severity of ecchymosis

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130812014333N195**
Registration date: **2023-01-29, 1401/11/09**
Registration timing: **prospective**

Last update: **2023-01-29, 1401/11/09**
Update count: **0**

Registration date
2023-01-29, 1401/11/09

Registrant information

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-02-04, 1401/11/15

Expected recruitment end date
2023-04-04, 1402/01/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of cold compress or pressure bandage, in addition to applying continuous local pressure, on the incidence and severity of hematoma and ecchymosis caused by radial artery sampling in the intensive care unit.

Public title
The effect of cold compress or compression bandage on the occurrence and severity of hematoma and ecchymosis caused by radial artery sampling.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age more than 18 years Allen test Systolic blood pressure below 180 Having a palpable pulse in the radial area of the wrist Informed consent
Exclusion criteria:
Coagulation disorders Presence of shunt or graft or fistula in upper limb areas Therapeutic use of heparin and warfarin Raynaud's syndrome Any skin, mucous or vascular damage in the hand to be sampled History of the vascular diseases in the upper limbs History of Hematoma History of infection, swelling, or ulceration in the radial area
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Using the simple random method. The names of the participants are written on the card. The cards are put into a box that cannot be seen from outside. One of the colleagues of the plan is asked to remove one card from the container at a time. The names of the 30 cards that are selected first are placed in the first intervention group, the second 30 selected cards are placed in the third intervention group, and the remaining 30 in the control group.
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 Islamic Azad University, Khorasgan branch
Street address
Vice Chancellor for Research Affairs, University Blvd., Arghwanieh, J Sharghi Street
City
Isfahan
Province
Isfehan
Postal code
8155139998
Approval date
2022-09-05, 1401/06/14
Ethics committee reference number
IR.IAU.KHUISF.REC.1401.210

Health conditions studied

1

Description of health condition studied
Bleeding
ICD-10 code
S06
ICD-10 code description
Intracranial injury

Primary outcomes

1

Description
Incidence and severity of hematoma
Timepoint
at time intervals of 1, 6, 12 and 48 hours after arterial blood sampling
Method of measurement
Using a transparent sheet, the dimensions of the bruise and hematoma are drawn on it, and then the area of the bruise and hematoma is measured and recorded on the millimeter paper.

2

Description
Incidence and severity of ecchymosis
Timepoint
at time intervals of 1, 6, 12 and 48 hours after arterial

blood sampling

Method of measurement

Using a transparent sheet, the dimensions of the bruise and hematoma are drawn on it, and then the area of the bruise and hematoma is measured and recorded on the millimeter paper.

Secondary outcomes

empty

Intervention groups

1

Description

In intervention group 1: After applying the routine treatment similar to the control group, a cold compress is used for 3 minutes

Category

Treatment - Other

2

Description

In intervention group 2: after applying the same routine treatment as the control group, it is closed using 3 relatively vertical elastic bandages.

Category

Treatment - Other

3

Description

Control group: Immediately after the needle exit, local pressure is applied with two fingers for 5 minutes using a 4 x 4 piece of gauze, if the bleeding continues, pressure will be applied until the bleeding stops completely

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Namazi Hospital

Full name of responsible person
Marziyeh Shokraei

Street address
Namazi Hospital, Namazi Square, Zand St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Dr. Majid Meshkini

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Grant name

Grant code / Reference number

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

Yes

Title of funding source
Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Marziyeh shokraei

Position
Nursing master's student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Dr. Maryam Radmehr

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Member of the faculty of Isfahan Azad University

Latest degree
Ph.D.

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Bachelor

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Nursery

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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
There is no further information

Study Protocol
No - There is not 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