

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

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

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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

AgeFrom **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

Isfahan

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

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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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Full name of responsible person

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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