

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Comparing the Effects of Wearing of Elastic Socks with Leg Elevation on preventing Hypotension in patients undergoing Plasmapheresis

Protocol summary

Study aim

Comparing the effects of wearing of elastic socks with leg elevation on preventing hypotension in patients undergoing plasmapheresis

Design

A randomized clinical trial that includes a control group with 3 methods ; wearing elastic socks, lower limb elevation and using both of them. Patients will be grouped in parallel permutation blocks. The number of samples are 35 people. Each patient is required to attend 4 sessions , so that 140 plasmapheresis sessions will be performed for all patients.

Settings and conduct

This study will be implemented to prevent hypotension caused by plasmapheresis; The study will be conducted in Sina hospital in Hamedan city, which includes all patients referring for plasmapheresis who have necessary qualifications for the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All Patients were candidates for plasmapheresis, at least 4 sessions in a day interval Age 20 to 60 years Minimum volume of plasma separation 1.5 liters Plasmapheresis time, 3 to 4 hours Patient alertness Exclusion criteria: Use of medications that affect blood pressure over the past 24 hours Any prohibition on measuring blood pressure and upper limb pulse Any prohibition on wearing elastic socks or lifting legs Pregnancy Patient's unwillingness to participate in the study Cardiovascular disease and severe anemia

Intervention groups

Method A, using of elastic socks Method B, raising the lower limbs Method C, simultaneous using of elastic socks and raising the lower limbs Method D, the control group

Main outcome variables

Blood pressure and pulse rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191020045166N1**

Registration date: **2020-01-17, 1398/10/27**

Registration timing: **registered_while_recruiting**

Last update: **2020-01-17, 1398/10/27**

Update count: **0**

Registration date

2020-01-17, 1398/10/27

Registrant information

Name

Armin mohamadiparsa

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3272 7710

Email address

armin94g@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-22, 1398/10/01

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the Effects of Wearing of Elastic Socks with Leg Elevation on preventing Hypotension in patients undergoing Plasmapheresis

Public title

The Effect of Nursing Interventions on the Preventing Hypotension in Patients Undergoing Plasmapheresis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

All patients undergoing plasmapheresis for at least 4 sessions with at least one day interval Age 20 to 60 years The minimum volume of plasma separation should be 1.5 liters The duration of plasmapheresis is between 3 and 4 hours Patient alertness

Exclusion criteria:

Cardiovascular disease and severe anemia Use of medications that affect blood pressure over the past 24 hours Any prohibition on measuring blood pressure and upper limb pulse Any prohibition on wearing elastic socks or lifting legs Pregnancy

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **35**

More than 1 sample in each individual

Number of samples in each individual: **4**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be grouped by permutation blocks, So that each combination of ABCD, BCAD, CDAB and DABC will be placed in a separate envelope to the same count of patient so at first we select a patient who chooses an envelope randomly; for example if ABCD sequence is selected, method A will be run at first then B and respectively C and D.

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 Hamedan University of Medical Sciences

Street address

Fahmide Street, Hamedan University of Medical Sciences

City

Hamedan

Province

Hamadan

Postal code

6517838698

Approval date

2019-10-28, 1398/08/06

Ethics committee reference number

IR.UMSHA.REC.1398.613

Health conditions studied

1

Description of health condition studied

Prevention of Hypotension due to Plasmapheresis

ICD-10 code

I95

ICD-10 code description

Hypotension

Primary outcomes

1

Description

Blood Pressure

Timepoint

Before starting the process and then at 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4 hours and finally half an hour after the end

Method of measurement

Portable Blood Pressure Monitor

2

Description

Pulse Rate

Timepoint

Before starting the process and then at 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4 hours and finally half an hour after the end

Method of measurement

Pulse Oximeter Device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group A: In addition to receiving routine care, the patient also uses elastic socks; at the beginning of the plasmapheresis session, the patient wears elastic socks and is maintained until the end of the session, Also at the start, during and after the intervention, the patient's blood pressure and pulse are recorded.

Category

Prevention

2

Description

Intervention group B: In addition to receiving routine care, the patient's legs are raised 45 degrees at the start of the session and this position is maintained until the end of the plasmapheresis and the patient's blood pressure and pulse rate are recorded during the session.

Category

Prevention

3

Description

Intervention group C: At the beginning of plasmapheresis, elastic socks are used to raise the legs 45 degrees simultaneously until the end of the session and the patient's blood pressure and pulse are recorded during plasmapheresis.

Category

Prevention

4

Description

Control group: The patient does not receive any intervention and only the routine care for patients during plasmapheresis will be implemented and the patient's blood pressure and pulse are recorded during the session

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital of Hamedan

Full name of responsible person

Mahyar Motaghd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Saeid Bashirian

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Shahid Fahmideh Boulevard

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Armin Mohamadiparsa

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Person responsible for updating data

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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

Undecided - It is not yet known if there will be 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

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

Analytic Code

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

Data Dictionary

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