

# 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

**Street address**

Mirzadeh Eshghi Street

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Hamedan

**Province**

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6516848741

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**Email**

farsh\_hamedan@umsha.ac.ir

**Web page address**

<http://fsh.umsha.ac.ir/>

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Saeid Bashirian

**Street address**

Shahid Fahmideh Boulevard

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**Email**

Info.Research@umsha.ac.ir

**Web page address**

<http://research.umsha.ac.ir/>

**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

### Contact

**Name of organization / entity**  
Hamedan University of Medical Sciences  
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Nurse  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Hamedan University of Medical Sciences

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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