

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

The effect of early rehydration on fatigue and thirst in patients undergoing plasmapheresis

Protocol summary

Study aim

Evaluation of the effect of prehydration on the fatigue and exhaustion of patients undergoing plasma therapy

Design

This cross-over interventional intervention is done. Patients undergoing Plasmapheresis are randomly assigned to one of two groups (first, a common fluid therapy, then a pre-term fluid therapy), or (b) an early treatment fluid, followed by a regular liquid therapy. At the start of the plasma milling and during it (by the researcher) and then (at home by a checklist that was previously trained to the patient by the method of completing it, until the next meeting is completed and will be delivered at the next meeting), the fatigue with The tool (RFS) and thirst are measured with the VAS visual simulation tool. In the usual fluid therapy, the plasma is first removed and the fluid is treated according to the protocol. In premature fluid therapy, 300 cc of the prescribed serum is first infused and the plasma is removed immediately, and the rest of the fluid is infused in accordance with the protocol during plasma therapy. This two-session procedure (each session is 2-4 hours) is repeated, and in the next two sessions, the fluid administration procedure is changed.

Settings and conduct

This cross-over interventional intervention is done. Patients undergoing Plasmapheresis are randomly assigned to one of two groups (first, a common fluid therapy, then a pre-term fluid therapy), or (b) an early treatment fluid, followed by a regular liquid therapy. At the start of the plasma milling and during it (by the researcher) and then (at home by a checklist that was previously trained to the patient by the method of completing it, until the next meeting is completed and will be delivered at the next meeting), the fatigue with The tool (RFS) and thirst are measured with the VAS visual simulation tool. In the usual fluid therapy, the plasma is first removed and the fluid is treated according to the protocol. In premature fluid therapy, 300 cc of the

prescribed serum is first infused and the plasma is removed immediately, and the rest of the fluid is infused in accordance with the protocol during plasma therapy. This two-session procedure (each session is 2-4 hours) is repeated, and in the next two sessions, the fluid administration procedure is changed.

Participants/Inclusion and exclusion criteria

Inclusion criteria The desire to participate in the study
Age between 18-60 years Iranian nationality Alert
Awareness of the person and time and place Use of the drug for a period of 4 hours before plasma therapy Have written consent to participate in the research. Ability to speak Persian Literacy reading and writing According to the prescribing physician, you need to carry out plasma therapy Drug addiction Exit criteria Get sedative medications such as midazolam Exercising physical activity or tolerating mental stress that causes fatigue Infections that cause weakness or fever like colds, allergies and ... Unwillingness to continue cooperation in the study Fewer than four sessions require plasma transcription Getting housing or sedation during the Plasmapheresis session

Intervention groups

Group A Group b

Main outcome variables

Decrease fatigue Reduce thirst

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170812035650N2**
Registration date: **2018-01-27, 1396/11/07**
Registration timing: **registered_while_recruiting**

Last update: **2018-01-27, 1396/11/07**

Update count: **0**

Registration date

2018-01-27, 1396/11/07

Registrant information

Name

manizheh hoseinzadeh

Name of organization / entity

Mashhad university of medical science

Country

Iran (Islamic Republic of)

Phone

+98 51 3871 1584

Email address

hoseinzadehgm1@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2018-01-03, 1396/10/13

Expected recruitment end date

2018-07-04, 1397/04/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of early rehydration on fatigue and thirst in patients undergoing plasmapheresis

Public title

evaluation of the effect of pre-hydration on the fatigue and exhaustion of patients undergoing plasma therapy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Be to Iran dont be addicted to not use housing

Exclusion criteria:

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

does not have

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of mashhad university of medical sciences

Street address

rezashahr

City

mashhad

Province

Razavi Khorasan

Postal code

9176936939

Approval date

2018-01-02, 1396/10/12

Ethics committee reference number

1396.254

Health conditions studied

1

Description of health condition studied

patient undergoing plasmapheresis

ICD-10 code

M35.9

ICD-10 code description

Autoimmune disease (systemic) NOS

Primary outcomes

1

Description

fatigue

Timepoint

during and after plasmapheresis

Method of measurement

with scale

2

Description

thirst

Timepoint

during and after plasmapheresis

Method of measurement

with scale

Secondary outcomes

1

Description

blood pressure

Timepoint

during plasmapheresis

Method of measurement

Barometer

Intervention groups

1

Description

early rehydration

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam reza hospital

Full name of responsible person

seyed reza mazloun

Street address

Daneshgah

City

mashhad

Province

Razavi Khorasan

Postal code

911111111

Phone

+98 51 3852 8514

Email

hoseinzadehgm1@mums.ac.ir

2

Recruitment center

Name of recruitment center

Qaem hospital

Full name of responsible person

seyed reza mazloun

Street address

Daneshgah

City

mashhad

Province

Razavi Khorasan

Postal code

911111111

Phone

+98 51 3852 8513

Email

hoseinzadehgm1@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

seyed reza mazloun

Street address

Daneshgah

City

mashhad

Province

Razavi Khorasan

Postal code

911111111

Phone

+98 51 3852 8513

Email

hoseinzadehgm1@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

10

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

mashhad university of medical science

Full name of responsible person

seyed reza mazloun

Position

Nursing Education master

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

nursing school

City

mashhad

Province

Razavi Khorasan

Postal code

911111111

Phone

+51 38591511

Fax

Email

MazlomSR@mums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

mashhad university of medical science

Full name of responsible person

seyed reza mazloum

Position

Nursing Education master

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

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91111111

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MazlomSR@mums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

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Web page address

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