

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effectiveness of plasmapheresis in treatment, hemodynamic, electrolyte parameters and the outcome of paraquat poisoned patients

Protocol summary

Study aim

Determining the effectiveness of plasmapheresis in the treatment and outcome of patients with paraquat poisoning

Design

A randomized, double-blinding clinical trial, with the parallel groups, Phase 3 on 80 patients

Settings and conduct

In this randomized double-blind clinical trial study, 80 patients with paraquat poisoning referred to the emergency department of Isfahan Khorshid Hospital will be included in the study and randomly divided into 2 groups. One group undergoes only routine treatment and the other group undergoes plasmapheresis in addition to routine treatment. Then blood pressure, electrolyte parameters, and coagulation parameters of patients will be evaluated and compared between the two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria include age over 18 years, oral paraquat poisoning, absence of more than 24 hours of intoxication, and consent to participate in the study. Exclusion criteria included having coagulation disorders, having a history of respiratory-pulmonary diseases, having previous lung injury, having seizures, and decreased consciousness or coma.

Intervention groups

Control group: In this group, patients undergo routine treatment including hemodialysis and administration of antioxidants including N-acetylcysteine, vitamin E, vitamin C, and methylprednisolone during hospitalization. Intervention group: In this group, in addition to the above treatment (as a routine treatment), patients are treated with plasmapheresis as follows. Plasmapheresis is a daily volume for 7 days, replaced with fresh plasma, after which plasmapheresis will be performed on alternating days as needed.

Main outcome variables

Blood pressure; Sodium; Potassium; Calcium; Magnesium; Creatinine; Platelets; White blood cell; Lymphocyte; Red blood cell

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200507047344N4**

Registration date: **2022-07-11, 1401/04/20**

Registration timing: **prospective**

Last update: **2022-07-11, 1401/04/20**

Update count: **0**

Registration date

2022-07-11, 1401/04/20

Registrant information

Name

shafeajafar zoofaghari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3268 7610

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-22, 1401/05/31

Expected recruitment end date

2023-03-21, 1402/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effectiveness of plasmapheresis in treatment, hemodynamic, electrolyte parameters and the outcome of paraquat poisoned patients

Public title

Effectiveness of Plasmapheresis on the treatment of paraquat poisoned patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age over 18 years Oral paraquat poisoning (confirmation of paraquat poisoning is determined by testing for urinary sodium dithionate test) No more than 24 hours after poisoning Satisfaction to participate in the study

Exclusion criteria:

Having coagulation disorders Having a history of respiratory-lung diseases Having a previous lung injury Having seizures, loss of consciousness or coma

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, 80 eligible patients will be randomly selected. Then, these patients will be randomly encoded using computer software called "Random Allocation" and automatically divided into two groups. The relevant codes will be entered in the raw checklists and each of these checklists will be randomly assigned to one patient and that patient will be randomly assigned to one of the two study groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the administration of plasmapheresis in one group and its non-administration in the other group, the intervener is aware of the type of intervention in each of the two groups. In addition, the patient is not aware of the difference in the type of treatment between the two groups. Also, the data collector and the data analyzer of the type of intervention in each group will not have any information.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezar Jarib street, Azadi square.

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Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2022-05-11, 1401/02/21

Ethics committee reference number

IR.MUI.MED.REC.1401.053

Health conditions studied**1****Description of health condition studied**

Paraquat poisoning

ICD-10 code

T60.3X1

ICD-10 code description

Toxic effect of herbicides and fungicides, accidental (unintentional)

Primary outcomes**1****Description**

Systolic blood pressure

Timepoint

Before the intervention and the first, third, fifth days after the intervention and during the discharge from the hospital

Method of measurement

Monitoring device

2**Description**

Diastolic blood pressure

Timepoint

Before the intervention and the first, third, fifth days after the intervention and during the discharge from the hospital

Method of measurement

Monitoring device

3

Description

Electrolytic parameters

Timepoint

Before the intervention and the first, third, fifth days after the intervention and during the discharge from the hospital

Method of measurement

Blood test

4

Description

Coagulation parameters

Timepoint

Before the intervention and the first, third, fifth days after the intervention and during the discharge from the hospital

Method of measurement

Blood test

Secondary outcomes

1

Description

Tachypnea

Timepoint

The first, third, fifth days after the intervention until discharge from the hospital

Method of measurement

Clinical examination

2

Description

Respiratory distress

Timepoint

The first, third, fifth days after the intervention until discharge from the hospital

Method of measurement

Clinical examination

3

Description

Hypocalcemia

Timepoint

The first, third, fifth days after the intervention until discharge from the hospital

Method of measurement

Clinical examination

Intervention groups

1

Description

Control group: In this group, patients undergoing routine treatment including hemodialysis and administration of antioxidants including N-acetylcysteine 300 mg/kg 24-hour daily infusion, vitamin E 300 units every 12 hours intramuscularly, and vitamin C 200 mg/h is given as an intravenous infusion and 1 gram of methylprednisolone daily during hospitalization. The dose of vitamin C in case of kidney involvement will be changed after consultation with a nephrologist.

Category

Treatment - Drugs

2

Description

Intervention group: In this group, in addition to the routine treatment, patients are treated with plasmapheresis as follows. Plasmapheresis is a daily volume for 7 days, replaced with fresh plasma, after which plasmapheresis will be performed on alternating days as needed.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Khorshid hospital

Full name of responsible person

Shafeajafar Zoofaghari

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Ostandari street.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mansour Siavash Dastjerdi

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Vice Chancellor for Research, School of Medicine, Hezar Jarib street, Isfahan

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Isfahan 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

Shafeajafar Zoofaghari

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Toxicology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Shafeajafar Zoofaghari

Position

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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