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

shafeajafar@med.mui.ac.ir

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 Plasmaphersis 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.
City
Isfahan
Province
Isfehan
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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81458-31451
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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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Isfahan

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dean@med.mui.ac.ir

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

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Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

Contact

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Shafeajafar Zoofaghari
Position
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Latest degree
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Other areas of specialty/work
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shafeajafar@med.mui.ac.ir

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