Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Evaluation and comparison of sucralfate effect in treatment of oral paraquat poisoning in comparison with non-prescribed oral poisoning.

Protocol summary

Study aim
Reduction the harmful effects of oral paraquat poisoning
Design
The present study is a randomized double-blind clinical trial.
Settings and conduct
The demographic characteristics of patients such as age, gender, smoking, poisoning time, and underlying diseases (diabetes, renal failure, heart failure) will be recorded. Then, in the first group, gastric lavage with sucralfate will be performed at the dose of 5 g in 2 liters water, and in the second group, gastric lavage will be performed without the use of sucralfate with tape water. For blinding of the study, both sucralfate solution and tape water are prepared in a certain amount and are labeled with letters B and A and are given to the intern to use them in gastric lavage. .
Participants/Inclusion and exclusion criteria
Inclusion criteria: 1- Age over 18 years 2- Oral poisoning with paraquat 3- No more than 24 hours after the poisoning 4- informed consent Output Criteria: 1. Having coagulation disorders 2. Having seizures, loss of consciousness or coma
Intervention groups
The intervention is gastric lavage with a solution of sucralfate (5 g) in water (2 liters).
Main outcome variables
The length of hospital stay, patients' vital signs (such as blood pressure, heart rate, and oxygen saturation), ALT, AST, Cr, BUN, sodium ditunite testing, chest x-ray on the first, third, fifth, tenth, and discharge day from the hospital will be evaluated and recorded.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20200507047344N1**
Registration date: **2020-07-13, 1399/04/23**
Registration timing: **prospective**

Last update: **2020-07-13, 1399/04/23**
Update count: **0**
Registration date
2020-07-13, 1399/04/23

Registrant information
Name
shafeajafar zoofaghari
Name of organization / entity
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Email address
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-09-22, 1399/07/01
Expected recruitment end date
2021-10-22, 1400/07/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation and comparison of sucralfate effect in treatment of oral paraquat poisoning in comparison with non-prescribed oral poisoning.

Public title
Effectiveness of sucralfate in treatment of oral paraquat

poisoning

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Oral paraquat poisoning During recent past day Informed consent

Exclusion criteria:

More than 24 hours have passed since the poisoning No consent

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

60 patients with paraquat poisoning who were eligible for inclusion in the study will be enrolled by the simple randomized method. Then they will be divided into two groups of 30 using the random block method with 3 blocks. So that the first three cases are separated and assigned to group one, then the next three cases are separated and assigned to group two and this will be continued three by three in the same way till the ending of samples.

Blinding (investigator's opinion)

Double blinded

Blinding description

Both the sucralfate and normal saline ingredients are pre-prepared to a certain extent and are labeled with the letters A and B and given to the resident to use on gastric lavage.

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 Ave, Azadi Square.

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8174673461

Approval date

2020-04-12, 1399/01/24

Ethics committee reference number

IR.MUI.RESEARCH.REC.1399.021

Health conditions studied

1

Description of health condition studied

Paraquat poisoning

ICD-10 code

T60.3X2A

ICD-10 code description

Toxic effect of herbicides and fungicides, intentional self-harm, initial encounter

Primary outcomes

1

Description

Lung involvement

Timepoint

See chest x-ray at the beginning of the entrance and on the third, fifth and seventh days of hospitalization and at the time of discharge

Method of measurement

Chest x-ray

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, gastric lavage with sucralfate will be performed at the rate of 5 grams per 2 liters of water. In this way, after preparing the Sucralfite solution in advance with the B label, the patient corresponding to this intervention, which is determined by randomization, is given gastric lavage.

Category

Treatment - Drugs

2

Description

Control group: A patient poisoned with oral paraquat is given gastric lavage without the use of a Sucralfate solution and only with water.

Category

Treatment - Drugs

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
Mojgan Mortazavi

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8174673461

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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
Esfahan 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
Fellowship of clinical toxicology

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Position
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Total data after deleting the names
When the data will become available and for how long
Since July 1401
To whom data/document is available
University researchers
Under which criteria data/document could be used
None
From where data/document is obtainable
shafeajafar@med.mui.ac.ir
What processes are involved for a request to access data/document
one month
Comments