

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 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

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

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.

City
Isfahan
Province
Isfahan
Postal code
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 Sucralfate 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

Street address

Ostandari street.

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81458-31451

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toxicology@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mojgan Mortazavi

Street address

Hezar Jarib Ave, Azadi Square.

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mortazavi@gmail.com

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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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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Person responsible for updating data

Contact

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Full name of responsible person

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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