Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of pulse therapy with glucocorticoids and cyclophosphamide in patients with paraquat poisoning

Protocol summary

Summary

The aim of the present study is to assess the effectiveness of repeated cyclosphosphamide (CP) and methylprednisolone (MP) combination in the treatment of paraquat (PQ) poisoning in a double-blind, randomized clinical trial. Eligible participants in this study are patients with moderate to severe PQ poisoning within 24 hours of hospitalization. Due to the unavailability of equipment to measure serum PQ levels, moderate to severe PQ poisoning is confirmed if urine samples turn dark blue in the urinary sodium dithionite test. Patients will be allocated in a random fashion between case and control groups. The sample size is calculated based on previous studies almost 46 patients. Taking any other poisons, underlying renal, hepatic, and pulmonary diseases, and unconsciousness are considered as exclusion criteria. All patients receive two cycles of eight hours hemoperfusion with charcoal, and undergo emergency hemodialysis in the fastest time possible. After the dialysis, the intervention group receive 15 mg/Kg CP for two days and 1g MP for three days. Each drug infuses in 200 cc dextrose saline 5 % during two hours. The control group receives routine, supportive care and 200 cc dextrose saline 5% infusion during two hours for three days as placebo. At the time of admission, demographic characteristics, history of underlying diseases, and time between PQ intake and the entrance to the emergency department are recorded. During the study daily measurement of liver function test, renal function test and blood gas are performed. Finally mentioned paraclinic findings and mortality between the two group are compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014012611873N2**

Registration date: **2014-03-17, 1392/12/26**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-03-17, 1392/12/26

Registrant information

Name

Amir Mandegar

Name of organization / entity

Ahvaz Jundishapur University of Medicine Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research,Ahvaz JondyShapor University of Medical Sciences

Expected recruitment start date

2013-01-20, 1391/11/01

Expected recruitment end date

2015-01-21, 1393/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of pulse therapy with glucocorticoids and cyclophosphamide in patients with paraquat poisoning

Public title

Efficacy of glucocorticoids and cyclophosphamide in the treatment of paraquat poisoning

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: approved the pesticide paraquat during the last 24; moderate to severe poisoning with this herbicide The exclusion criteria: In addition to any other pesticide paraquat; the underlying liver disease - kidney - lung; The incidence of treatment-related complications during interventional treatment

Age

From **15 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahvaz Jondishapour University of Medical Sciences

Street address

Esfand St, Golestan Blv.

City

Ahvaz

Postal code

Approval date

2012-09-22, 1391/07/01

Ethics committee reference number

u-91112

Health conditions studied

1

Description of health condition studied

poisoning with the pesticide paraquat

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Kidney failure

Timepoint

Daily during treatment

Method of measurement

BUN & Cr..Cr: 1.4 mg/dl (i.e., mean normal value + 2 standard deviations).

2

Description

Mortality

Timepoint

Constantly during treatment

Method of measurement

Observation

3

Description

Hepatitis (liver failure)

Timepoint

Daily during treatment

Method of measurement

(ST) and(ALT) values were > 70 U/L (normal valueis < 35 U/L) or when total bilirubin was > 3.0 mg/dl (normal valueis < 1.4 mg/dl).

4

Description

hypoxia

Timepoint

Daily during treatment

Method of measurement

PaO2 < 80 mm Hg at roomair.

Secondary outcomes

empty

Intervention groups

1

Description

ent emergency hemodialysis in the fastest time possible. After the dialysis, the intervention group received 15 mg/Kg CP for two days and 1g MP for three days. Each drug infused in 200 cc dextrose saline 5 % during two hours.

Category

Treatment - Drugs

2

Description

After the initial measures, including gastric lavage and administration of activated charcoal and two charcoal dialysis. The control group consisted of normal saline placebo is used, 200 cc given intravenously over two hours to three days is prescribed.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi hospital

Full name of responsible person

Ahmsd Ghorbani

Street address

Razi Hospital, Palestine St.

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz JondyShapour University of Medical Sciences

Full name of responsible person

Dr Mostafa Feghhi

Street address

Vice chancellor for research,Ahvaz JondyShapour University of Medical Sciences, Ahvaz, golestan Golestan Blvd, Ahvaz

City

Ahvaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz JondyShapour University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Ahvaz Jondishapour University of Medical Sciences

Full name of responsible person

Dr Ahmad Ghorbani

Position

Forensic and clinical toxicologist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty