

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The study of fresh frozen plasma (FFP) and albumin on oxidative stress biomarkers in organophosphorous pesticide poisoning

Protocol summary

Summary

The aim of this study will be evaluated the effect of FFP and albumin in organophosphate poisoning with an approach to the plasma cholinesterase level and oxidative stress biomarkers. Inclusion criterias included history and clinical signs of organophosphates poisoning and reduce acetyl cholinesterase level and exclusion criteria included chronic liver diseases and pregnancy. On the basis of organophosphate poisoned patients who will be admitted to farshchian sina hospital of Hamadan province of Iran; 60 patients will be selected and divided into three groups: control and two interventional groups. The control group will be underwent conventional treatments (atropine and pralidoxime), the first interventional group will be recieved conventional therapy with fresh frozen plasma and second interventional group will be recieved conventional therapy with albumin for 3 days. In the meantime, acetyl cholinesterase levels will be measured daily and finally after termination of treatment oxidative stress biomarkers will be assessed .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016121131347N1**

Registration date: **2017-05-22, 1396/03/01**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-05-22, 1396/03/01

Registrant information

Name

Saeed Afzali

Name of organization / entity

Hamadan University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 3827 4191

Email address

afzali@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Hamadan University Of Medical Sciences

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2018-04-21, 1397/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The study of fresh frozen plasma (FFP) and albumin on oxidative stress biomarkers in organophosphorous pesticide poisoning

Public title

The study of fresh frozen plasma (FFP) and albumin on oxidative stress biomarkers in organophosphorous pesticide poisoning

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Clinical symptoms and signs with organophosphates poisonig ;Reduce of acetylcholine esterase level ; Age 20-40 Y exclusion criteria: Chronic disease Patients ; Smoking , Pregnancy and Lactation ; Admitted after 12 hour of poisoning ; Drugs (succinyl

choline ,phenothiazines,antihistamines)

Age

From **20 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Hamadan University Of Medical Sciences

Street address

Vice-Chancellor For Research and Technology -
Mahdiah Street

City

Hamadan

Postal code

Approval date

2017-03-04, 1395/12/14

Ethics committee reference number

IR.UMSHA.REC.1395.568

Health conditions studied

1

Description of health condition studied

Toxic effect of pesticides

ICD-10 code

T60.0

ICD-10 code description

Organophosphate and carbamate insecticides

Primary outcomes

1

Description

Acetylcholine esterase

Timepoint

Before and after treatment

Method of measurement

Blood level

Secondary outcomes

1

Description

Oxidative stress biomarker

Timepoint

After treatment

Method of measurement

Blood sample

Intervention groups

1

Description

Control group: Conventional treatment : atropine and pralidoxime

Category

Treatment - Drugs

2

Description

First patient group: Conventional treatment with 3 units fresh frozen plasma for 3 days

Category

Treatment - Drugs

3

Description

Second patient group: Conventional treatment with 100 mililiters albumin 20% for 3 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Poisoning ward - Farshchian Sina Hospital

Full name of responsible person

Saeed Afzali

Street address

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamadan University Of Medical Sciences

Full name of responsible person
Saeed Bashirian

Street address
Mahdieh Street

City
Hamadan

Grant name

Grant code / Reference number

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

Title of funding source
Hamadan 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
Hamadan University Of Medical Sciences

Full name of responsible person
Saeed Afzali

Position
Associated Professor

Other areas of specialty/work

Street address
Poisoning Ward - Farshchian Sina Hospital-
Mirzadeheshghi Ave.

City
Hamadan

Postal code

Phone
+98 81 3827 4191

Fax

Email
<http://fsh.umsha.ac.ir/>

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Hamadan University Of Medical Sciences

Full name of responsible person
Akram Ranjbar

Position
PHD

Other areas of specialty/work

Street address
Pharmacy Faculty - Mahdieh Ave.

City
Hamadan

Postal code

Phone
+98 81 3838 1675

Fax

Email
<http://pharmacy.umsha.ac.ir/>

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Hamadan University Of Medical Sciences

Full name of responsible person
Saeed Afzali

Position
Clinical Toxicologist

Other areas of specialty/work

Street address
Poisoning Ward , Farshchian Sina Hospital
,Mirzadeheshghi Ave.

City
Hamadan

Postal code
6516748741

Phone
+98 81 3827 4191

Fax

Email
afzali691@yahoo.com

Web page address

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