

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Evaluation of intravenous vitamin C administration on methadone excretion in methadone toxicity patients

Protocol summary

Study aim

Determining the effect of intravenous vitamin C administration on methadone excretion in methadone poisoning patients

Design

Clinical trial with control group, with parallel, randomized groups, phase 2-3 on 54 patients. The random number table was used for randomization.

Settings and conduct

Patients with methadone poisoning who go to Shahid Mostafa Khomeini Hospital will be included in the study. Patients with a history of kidney stones, hemochromatosis, G6PD deficiency, iron overload, and diabetes will be excluded or considered as a control group. Patients who have used a drug or other toxin other than methadone are also excluded. Then 18 patients will be given 12 g of IV Vit C daily (in divided doses of 3 g every 6 hrs), 18 patients will be given 24 g (in divided doses of 6 g every 6 hrs), and 18 patients will not receive any Vit C. Serum levels of methadone and urine pH will be measured at the time of admission and 24 hours after admission (after receiving the fourth dose of vitamin C).

Participants/Inclusion and exclusion criteria

396/5000 Patients with methadone poisoning who visit Shahid Mostafa Khomeini Hospital in Ilam will be included in the study. Patients with a history of kidney stones, hemochromatosis, G6PD deficiency, iron overload, and diabetes will be excluded from the study or treated as a control group to avoid injustice. Patients who have used a drug or other toxin other than methadone are also excluded.

Intervention groups

Eighteen patients will be given 12 grams of intravenous vitamin C daily (in divided doses of 3 g every 6 hours), eighteen patients will be given 24 grams of intravenous vitamin C daily (in divided doses of 6 g every 6 hours), and eighteen patients as a control group will not receive vitamin C.

Main outcome variables

Decreased serum methadone levels; Decreased pH of urine

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200621047863N1**

Registration date: **2020-07-02, 1399/04/12**

Registration timing: **registered_while_recruiting**

Last update: **2020-07-02, 1399/04/12**

Update count: **0**

Registration date

2020-07-02, 1399/04/12

Registrant information

Name

maryam sadat hashemi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 84 3222 7134

Email address

m.s.hashemi86@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2020-07-22, 1399/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of intravenous vitamin C administration on methadone excretion in methadone toxicity patients

Public title
Evaluation of intravenous vitamin C administration on methadone excretion

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
All patients with methadone poisoning
Exclusion criteria:
History of kidney stones, hemochromatosis, G6PD deficiency, iron overload and diabetes Consumption of another substance in addition to methadone

Age
No age limit

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **54**

Randomization (investigator's opinion)
Randomized

Randomization description
Permuted block randomization of individuals using statistical software

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
Iran National Committee for Ethics in Biomedical Research
Street address
Medical School, Ilam University of Medical Sciences Campus, Pazhoohesh Boulevard, Bangamjab, Ilam
City
Ilam
Province

Ilam
Postal code
6939177143
Approval date
2020-06-21, 1399/04/01
Ethics committee reference number
IR.MEDILAM.REC.1399.106

Health conditions studied

1

Description of health condition studied

methadone poisoning

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Serum methadone levels

Timepoint

24 hours after the first dose of vitamin C (6 hours after the last dose)

Method of measurement

Laboratory measurement of serum vitamin C level and urine pH

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: 18 patients will receive 12 g of intravenous vitamin C (in divided 3 g doses every 6 hours)

Category

Treatment - Drugs

2

Description

Second Intervention Group: 18 patients will receive 24 g of intravenous vitamin C (in divided 6 g doses every 6 hours)

Category

Treatment - Drugs

3

Description

Control group: 18 patients will receive no vitamin C as the control group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Mostafa Khomeini

Full name of responsible person

Maryam Sadat Hashemi

Street address

Shahid Mostafa Khomeini Hospital, Shahed Hill,
Shahid Keshvari Square

City

Ilam

Province

Ilam

Postal code

6931934833

Phone

+98 84 3333 8228

Email

m.s.hashemi86@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ilam University of Medical Sciences

Full name of responsible person

Mohammadreza Kaffashian

Street address

Medical School, Ilam University of Medical Sciences
Campus, Pazhoohesh Boulevard, Bangamjab

City

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6931851147

Phone

+98 84 3222 7134

Email

M_R_KAFFASHIAN@yahoo.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Ilam 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

Ilam University of Medical Sciences

Full name of responsible person

Maryam Sadat Hashemi

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

Medical School, Ilam University of Medical Sciences
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

How to run the study, contextual variables and information about the consequences and results can be published.

When the data will become available and for how long

3 months after publishing the results

To whom data/document is available

All university interested people

Under which criteria data/document could be used

There are no specific restrictions

From where data/document is obtainable

m.s.hashemi86@gmail.com

What processes are involved for a request to access data/document

Send request to email. within 2 weeks

Comments