Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
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6931934833

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+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

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6931851147

Phone
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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

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

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Person responsible for updating data

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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