

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of intravenous calcium gluconate on abdominal pain among oral opium users suspected to lead poisoning

Protocol summary

Study aim

Investigating the effect of intravenous calcium gluconate on the reduction of abdominal pain in patients with opioid ingestion who suspect lead contamination

Design

This study, which is a clinical trial study, will be performed in 50 patients with oral opium with a lead level above 20 referring to the emergency department of Afzalipour Kerman Hospital and poisoning in Loghman Hospital. The sampling will be easy and accessible. The study will be initially explained in terms of the process and objectives of the study and will be included in the study once written consent is formally completed.

Settings and conduct

This study, which is a clinical trial study, will be carried out in 50 patients with oral hypertension with a lead level of more than 20 who are referred to emergency department of Afzali Pourkerman Hospital and poisoning in Loghman Hospital.

Participants/Inclusion and exclusion criteria

Inclusion criteria 1_Above 18 years old 2_Oral opium consumer with a lead level greater than 20 Exclusion criteria 1. Mental retardation 2- Neuropathic diseases such as diabetes 3. Chronic pain syndromes 4. High blood pressure and heart disease 5- Contraindications for calcium gluconate injection, including sensitivity to this group of drugs. Kidney stones. Hybercalcemia. Hipophosphatemia 6-pregnant patient 7-Patient with Asthma 8 - Patients suspected bowel obstruction or with sign of acute abdomen 9. History of Morphine Sensitivity 10-Other diagnosis other than lead poisoning 11. Use of psychiatric drugs 12. Chronic severe anemia

Intervention groups

patient who were injected morphine under cardiac monitoring and pulse oximetry where also recieved calcium gluconate

Main outcome variables

lead poisinig ; abdominal pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171009036661N2**

Registration date: **2018-05-27, 1397/03/06**

Registration timing: **retrospective**

Last update: **2018-05-27, 1397/03/06**

Update count: **0**

Registration date

2018-05-27, 1397/03/06

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3335 6220

Email address

m.mayel@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-06-02, 1396/03/12

Expected recruitment end date

2018-03-11, 1396/12/20

Actual recruitment start date

2017-06-02, 1396/03/12

Actual recruitment end date

2018-03-11, 1396/12/20

Trial completion date

empty

Scientific title

The effect of intravenous calcium gluconate on

abdominal pain among oral opium users suspected to lead poisoning

Public title

Evaluation of calcium gluconate on reduction of abdominal pain caused by lead toxicity

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

People over 18 years old Oral users of opioids with a lead level greater than 20

Exclusion criteria:

1. Mental retardation Neuropathic diseases such as diabetes Chronic pain syndromes High blood pressure and heart disease Contraindications for calcium gluconate injection, including sensitivity to this group of drugs. Kidney stones. Hypercalcemia. Hypophosphatemia. pregnant patient Patient with Asthma Patients suspected of obstructive bowel obstruction or with acute abdominal symptoms Other diagnosis other than lead poisoning Use of psychiatric drugs Chronic severe History of Morphine Sensitivity

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **50**

Actual sample size reached: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

...

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients will be divided into two groups, the first group of patients who will be injected with morphine and normal saline for relief of abdominal pain, will be injected with cardiac monitoring and pulse oximetry, and 0.1 mg / kg of morphine will be given slowly to the patient, The second group was the patients who underwent cardiac monitoring and pulse oximetry of 10cc calcium gluconate after injection of morphine with a microtiter. Before injection, the VAS is determined in each patient. Then the medicine is prescribed. After injection, the VAS will be measured at 15 minutes, 30 minutes, and one hour later.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kerman University of Medical Sciences

Street address

Somayyeh Crossroad (Tahmasebabad) , Beginning of Jihad Boulevard

City

kerman

Province

Kerman

Postal code

7613747181

Approval date

2017-04-29, 1396/02/09

Ethics committee reference number

IR.KMU.REC.1396.2116

Health conditions studied

1

Description of health condition studied

Lead toxicity in opium addicted patients

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

lead colic

Timepoint

15 minutes, 30 minutes and an hour later

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients who underwent cardiac monitoring and pulsed oximetry of 10cc calcium gluconate after injection of morphine with a microtiter. Before injection, the VAS is determined in each patient. Then the medicine is prescribed. After injection, the VAS will be measured at 15 minutes, 30 minutes, and one hour later.

Category

Treatment - Drugs

2**Description**

Control group: : Patients who received morphine 0.1 mg / kg and normal saline with micro-set for relief of abdominal pain which will be injected under cardiac monitoring and pulse oximetry

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Loghman hakim hospital

Full name of responsible person

Hasan hasaneian

Street address

Four Way Makhsoos Streets Unit , Loghman Hakim Hospital

City

Tehran

Province

Tehran

Postal code

1333631151

Phone

+98 21 5541 9005

Fax

+98 21 5541 7547

Email

loghman.hospital@sbmu.ac.i

2**Recruitment center****Name of recruitment center**

Afzalipour Hospital

Full name of responsible person

Masoud Mayel

Street address

Imam Highway

City

Kerman

Province

Kerman

Postal code

۷۶۱۶۹۱۳۹۱۱

Phone

+98 34 3325 7651

Email

masoud.mayel@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Kerman University of Medical Sciences

Full name of responsible person

dr. pardakhti

Street address

Tahmasebabad Four Way Deputy of research and technology

City

kerman

Province

Kerman

Postal code

7613747181

Phone

+98 34 3223 5011

Email

masoud.mayel@gmail.com

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

Yes

Title of funding source

Kerman 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**

Kerman University of Medical Sciences

Full name of responsible person

Dr. Massoud mayel

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

Street address

National Garden Square . Qarani Street

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Postal code

7613747181

Phone

+98 34 3223 5011

Email

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Dr. Massoud mayel

Position

Assistant Professor

Latest degree

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Person responsible for updating data

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Position

Assistant Professor

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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

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

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

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

Analytic Code

Not applicable

Data Dictionary

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