Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

Pharmacokinetic of intamuscular and intravenous methadone in critically ill patients

Protocol summary

Summary

The aim of this study is to compare the pharmacokinetic parameters of intravenous and intramuscular methadone in critically ill patients. The study is designed as prospective, open label, and is performed on 40 critically ill patients in ICU, who receive opioid for their pain. Patients should be younger than 65 years old and should not suffer renal or hepatic failure, also they should not have prior history of allergy to methadone. Patients are randomly assigned to two groups; one will receive IV methadone and the other one will receive IM methadone. Blood samples will be collected on the first and sixth day of the study, inorder to measure methadone blood level. The first consequence of this study would be methadone plasma concentration, and the second one is pharmacokinetic parameters based on plasma concentrations.

General information

Acronym

Pharmacokinetic of methadone in critically ill patients

IRCT registration information

IRCT registration number: **IRCT2013012610817N3**
Registration date: **2013-06-28, 1392/04/07**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-06-28, 1392/04/07

Registrant information

Name

Kourosh Sadeghi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8849 1340

Email address

sadeghik@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Siences

Expected recruitment start date

2013-02-19, 1391/12/01

Expected recruitment end date

2013-08-23, 1392/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Pharmacokinetic of intamuscular and intravenous methadone in critically ill patients

Public title

Pharmacokinetic of methadone in critically ill patients

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criterion: critically ill patients in ICU, who require pain management with opioids. Exclusion criteria: hypersensitivity to methadone or any component of the formulation; patients older than 65 years old; patients with renal failure(Scr > 2mg/dl ,Urine Output <0.5cc/kg/hour) 4.); patients with hepatic failure(hepatic enzymes more than 3 times normal); patients with Platelet less than 100000; mean arterial pressure less than 65 or who require inotrope or vasopressor and patient who suffer ALI (PaO2 /FIO2<300).

Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tehran University of Medical Siences
Street address
Tehran University of Medical Siences, Enghelaab Square, Tehran
City
Tehran
Postal code
Approval date
2013-06-02, 1392/03/12
Ethics committee reference number
20299

Health conditions studied

1

Description of health condition studied
critically ill patients in ICU
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Plasma methadone concentration
Timepoint
1st and 6th day of the study
Method of measurement
chromatography

2

Description
Methadone plasma concentration
Timepoint
on 1st and 6th day, 1,4, 8 and 12 hours after the last dose
Method of measurement
HPLC

Secondary outcomes

empty

Intervention groups

1

Description
Control, in this group , intramascular methadone is given to patients every 8 hour, in order to control their pain
Category
Treatment - Drugs

2

Description
Intervention, in this group, methadone is administerd to patients via intravascular route,5mg every 8 hour, to control their pain
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina Hospital
Full name of responsible person
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Siences
Full name of responsible person
fatemeh saeedi
Street address
Tehran University of Medical Siences, Enghelab Square, Tehran
City
Tehran

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Siences
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
tehran university of medical sciences
Full name of responsible person
Dr kourosh sadeghi
Position
clinical pharmacist
Other areas of specialty/work
Street address
pharmacy faculty of tehran university of medical schools 16 azar street , enghelab square Tehran,
City
tehran
Postal code
Phone
+98 21 6695 9090
Fax
Email
sadeghik@razi.tums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
tehran university of medical sciences
Full name of responsible person
Dr. mojtaba Mojtahedzadeh
Position
clinical pharmacist
Other areas of specialty/work
Street address
, Sina hospital, Hassan abad street,Imamkhomeini square,Tehran
City
Tehran
Postal code
Phone
+98 21 6634 8555
Fax
Email
mojtahed@tums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Azin Gheimati
Position
pharmacy student
Other areas of specialty/work
Street address
Tehran University of Medical Sciences,Enghelab square,Tehran
City
Tehran
Postal code
Phone
+98 886066200210098
Fax
Email
AZIN_GHEIMATI@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