Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Jun 2026

Comparison effect of submucosal injection and intravenous injection of ketamine on conscious sedation in patients who need wound repair in emergency department

Protocol summary

Study aim
determination and comparison of effect of submucosal injection and intravenous injection of ketamine in depth of sedation average

Design
randomised contoroled clinical trial, 4 arm parallel group

Settings and conduct
184 patients who are candidate for diagnostic therapeutic procedures in Emergency Department (ED) of Alzahra and Kashani hospital will be divided in to 4 groups: IV group (group1), 2,3,4 mg/kg submucousal group (group2,3,4). Depth of sedation will be measured during procedure.

Participants/Inclusion and exclusion criteria
Inclusion criteria:2-8 years old patients without IV line before emergency department enterance parents informed consent for study participation Exclusion criteria:ketamin sensitivity, physical or mental disability, immune systme diseases, another necessity for IV line fixation for patient, hypertension, recent seziures, thyroid diseases, glaucoma or acute globe injury, psychopathy, history of airway instability and tracheal stenosis, major procedures that cause posterior nasopharyngeal stimulation, active lung and upper airway infection, cardiovascular disease such as cardiac failure and angina pectoris, porphyria, major head trauma, CNS tumor, hydrocephalus

Intervention groups
IV group (group1), 2,3,4 mg/kg submucousal group (group2,3,4)

Main outcome variables
depth of sedation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20171211037834N2**
Registration date: **2019-11-25, 1398/09/04**
Registration timing: **retrospective**

Last update: **2019-11-25, 1398/09/04**
Update count: **0**

Registration date
2019-11-25, 1398/09/04

Registrant information

Name
Mahdi ebrahimi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 31 3771 8986

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m.ebrahimi@resident.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-09-23, 1398/07/01

Expected recruitment end date
2019-10-06, 1398/07/14

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison effect of submucosal injection and intravenous injection of ketamine on conscious sedation

in patients who need wound repair in emergency department

Public title
Comparison effect of submucosal injection and intravenous injection of ketamine on conscious sedation
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
children who are candidates for wound repair patients without IV line before emergency department enterance parents informed consent for study participation 2-8 years old
Exclusion criteria:
ketamin sensitivity physical or mental disability immune systme diseases another necessity for IV line fixation for patient hypertension recent seziures thyroid diseases glaucoma or acute globe injury psychopathy history of airway instability and tracheal stenosis major procedures that cause posterior nasopharyngeal stimulation active lung and upper airway infection cardiovascular disease such as cardiac failure and angina pectoris porphyria major head trauma, CNS tumor, hydrocephalus
Age
From **2 years** old to **8 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **184**
Randomization (investigator's opinion)
Randomized
Randomization description
simple individualized randomization with random allocation 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
Ethics committee of Isfahan University of Medical Sciences
Street address
hezarjirib Avenue
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2017-02-22, 1395/12/04
Ethics committee reference number
ir.mui.rec.1396.3.110

Health conditions studied

1

Description of health condition studied
sedation depth by ketamin in wound repair
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
sedation depth average
Timepoint
during procedure
Method of measurement
Ramsey score

Secondary outcomes

1

Description
frequency distribution of doctors satisfaction
Timepoint
after procedure
Method of measurement
very bad(0), bad(1), usual(2), good(3), very good(4)

2

Description
systolic blood pressure average
Timepoint
before, during, 5-10-15-30 min after injection
Method of measurement
Sphygmomanometer

3

Description
heart rate average
Timepoint
before, during, 5,10,15,30 min after injection
Method of measurement
cardiac monitor

4

Description
O2 saturation percent average
Timepoint
before, during, 5-10-15-30 min after injection
Method of measurement
pulse oximetry

5

Description
respiratory rate average
Timepoint
before, during, 5-10-15-30 min after injection
Method of measurement
respiration in 1 minute

6

Description
admition duration average
Timepoint
during discharge
Method of measurement
admition duration in minute

7

Description
sedation duration average
Timepoint
during sedation
Method of measurement
since the patient dose not obey orders until the patient obeys orders again

8

Description
sedation onset average
Timepoint
drug administration
Method of measurement
from drug administration to disobedience onset

Intervention groups

1

Description
Control group: 1.5 mg/kg ketamin, rotexmedica Germany company production and with 28 gauge syringe intravenously
Category
Treatment - Drugs

2

Description
Intervention group: 2mg/kg ketamin, rotexmedica Germany company production and with 28 gauge syringe submocousally
Category
Treatment - Drugs

3

Description
Intervention group: 3mg/kg ketamin, rotexmedica Germany company production and with 28 gauge syringe submocousally
Category
Treatment - Drugs

4

Description
Intervention group: 4mg/kg ketamin, rotexmedica Germany company production and with 28 gauge syringe submocousally
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra hospital
Full name of responsible person
Mahdi Ahmadpoor
Street address
Shohadaye Sofe avenue
City
Isfahan
Province
Isfehan
Postal code
8174675731
Phone
+98 31 3668 5555
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Email
alzahra@mui.ac.ir
Web page address
http://alzahra.mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Ahmad Movahedian Attar
Street address
No 4 building, Isfahan university of medical science, Hezarjirib Avenue
City
Isfahan
Province

Isfehan

Postal code
81746-73461

Phone
+98 31 3668 8138

Email
research@mui.ac.ir

Web page address
http://research.mui.ac.i

Grant name

Grant code / Reference number

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

Title of funding source
Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Mahdi Ahmadpour

Position
Resident of Emergency Medicene

Latest degree
Medical doctor

Other areas of specialty/work
Emergency Medicine

Street address
Unit 411, Mahtab Residential Complex, Ghadir Blvd, Sepahan Shahr

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8179949841

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not 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
No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

all of data will be Shareable after unrecognizable patients.

When the data will become available and for how long

data will be available 1 year after release.

To whom data/document is available

data will be available just for research centers of universities.

Under which criteria data/document could be used

analysis is permitted and special condition is not considered.

From where data/document is obtainable

availability request should be send via email with Introduction letter from research center.

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

after request email received, an email for identity confirmation will be sent to research center.In case of confirmation, data will be send via email.

Comments