

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 controlled 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 submucosal 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 entrance parents informed consent for study participation Exclusion criteria: ketamine sensitivity, physical or mental disability, immune system diseases, another necessity for IV line fixation for patient, hypertension, recent seizures, 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 submucosal 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)

Phone

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Email address

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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 entrance parents informed consent for study participation 2-8 years old

Exclusion criteria:

ketamin sensitivity physical or mental disability immune system diseases another necessity for IV line fixation for patient hypertension recent seizures 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

Isfahan

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

admission duration average

Timepoint

during discharge

Method of measurement

admission 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 submocusally

Category

Treatment - Drugs

3

Description

Intervention group: 3mg/kg ketamin, rotexmedica Germany company production and with 28 gauge syringe submocusally

Category

Treatment - Drugs

4

Description

Intervention group: 4mg/kg ketamin, rotexmedica Germany company production and with 28 gauge syringe submocusally

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

Isfahan

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<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

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Isfahan

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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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mahdi Ahmadpour

Position

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Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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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