

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of pain relief and sedation midazolam, ketamine with propofol during needle biopsy of kidney in childhood

Protocol summary

Summary

Objective: Investigation of the effect of pain relief and sedation midazolam/ketamine with propofol/fentanyl during needle biopsy of kidney in children. This study is a clinical trial. Seventeen patients referring to Dr. Sheikh Hospital, were randomly allocated to two treatment groups and no blinding is done. The criteria for inclusion are, patients undergoing renal biopsy and between the age of 3 to 16 years old. Exclusion criteria are, prohibition from the use of ketamine, the use of narcotic analgesics, drug allergy and unwillingness for participation in the experiment. The first group and the second group will be tested with midazolam/ketamine and propofol/fentanyl respectively. Results of the study will be: degree of pain in patients based on SAS criteria, degree of patients' calmness, degree of itching after 1, 3 and 6 hours after biopsy.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201610247892N5**

Registration date: **2017-03-11, 1395/12/21**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-03-11, 1395/12/21

Registrant information

Name

Anoosh Azarfar

Name of organization / entity

Mashhad University of Medical Sciences, Faculty of Nursing and Midwifery

Country

Iran (Islamic Republic of)

Phone

+98 51 1606 1227

Email address

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Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2017-01-20, 1395/11/01

Expected recruitment end date

2017-03-19, 1395/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of pain relief and sedation midazolam, ketamine with propofol during needle biopsy of kidney in childhood

Public title

Pain relief and sedation effect of midazolam/ketamine and propofol during needle biopsy of kidney in childhood

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: candidate renal biopsy; aged 16.3 years Exclusion criteria: to prohibit the use of ketamine (a history of schizophrenia-surgical complications in the chip-history of problems and heart failure, glaucoma, history of lung disease such as severe asthma); of painkillers such as opioids; history of drug sensitivity; unwillingness to participate in the 5-under anesthesia in the operating room where the biopsy done.

Age

From **3 years** old to **16 years** old

Gender

Both

Phase

2-3

Groups that have been masked*No information***Sample size**Target sample size: **17****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**

Ethics Committee of Mashhad University of Medical Sciences

Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah Street

City

Mashhad

Postal code

99191-91778

Approval date

2015-01-09, 1393/10/19

Ethics committee reference number

911040

Health conditions studied**1****Description of health condition studied**

Effect of pain relief and sedation

ICD-10 code

N18.9

ICD-10 code description

Chronic kidney disease, unspecified

Primary outcomes**1****Description**

The degree of pain-relieving itching -level of patient

comfort

Timepoint

One houe-3 hour- 6 hour after biopsy

Method of measurement

Scoring face pain assessment

Secondary outcomes**1****Description**

Itching

Timepoint

1 hour-3 hour--6hour

Method of measurement

Face evaluation

Intervention groups**1****Description**

Intervention group: received propofol/fentanyl in doses of 0.5 to 1 mg per kg body weight.

Category

Treatment - Drugs

2**Description**

Control group: midazolam/ketamine at doses of 30 to 50 micrograms and 0.25 to 1 mg per kg body weight.

Category

Treatment - Drugs

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

Dr.Sheikh Hospital

Full name of responsible person**Street address**

Dr. Sheikh Hospital, Tohid Squire, Motahari Street

City

Mashhad

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

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

City

Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad University of Medical Sciences

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

Mashhad University of Medical Sciences

Full name of responsible person

Yalda Ravanshad

Position

Community Medicine

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Anoosh Azarfara

Position

Associated professor

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Nayere Toosi

Position

Pediatrics residents

Other areas of specialty/work

Street address

169 number, Toofigh 15, Shahid Sadeghi street 10.

City

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Phone

00

Fax

Email

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