Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jun 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

azarfara@mums.ac.ir

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 Squre, 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

Street address

Clinical Research Development Unit, Quam Hospital, Ahmad Abad Avenue

City

Mashhad

Postal code

Phone

+98 915 301 7977

Fax

Email

ravanshady@mums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Anoosh Azarfar

Position

Associted proffesor

Other areas of specialty/work

Street address

Dr. Sheikh Hospital, Tohid Square, Motahari Avenue

City

Mashhad

Postal code

Phone

+98 51 3726 9021

Fax

Email

azarfara@mums.ac.ir

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

Mashhad

Postal code

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