

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Efficacy measurement of Intravenous Ibuprofen versus Intravenous Ketorolac in Patient Renal Colic Admittend in Emergency Department

Protocol summary

Study aim

Efficacy measurement Of Intravenous Iboprofen Versus Intravenous Ketorolac In Patient Renal Colic Admittend In Emergency Department

Design

In This Research Patients were divided Into 2 groups A&B Acuording to Block Randomise Method &SamplesInclude 240 Renal Colic Patient between 18 to 65 years old.

Settings and conduct

Patients were Checked Pursunt to Reduce Severity of Pain by VAS before Drug Injection &After 15 ,30,60 minuts after that.This Research has been done at Emergency Department of Shohadaie Tajrish Hospital In 1395 ,96 In Tehran.

Participants/Inclusion and exclusion criteria

Admitance Requirement:Every Adults with Renal Colic Diagnosis --Age between 18 to65 years old Non Admitance Requirement:Having Alergy to Ketorolac &Ibuprofen--Non cooperation to DetermineSeverity of Pain by VAS--Pregnancy-- Having background of Heart disease &HTN--Advanced Systemic disease--Malignancy - -Chronic Hepatic disease--Having background of Psychiatric &Norologic disease--Use of NSAID at 6 hours ago.

Intervention groups

1--Injection 30 mg Intravenous ketorolac In Group B 2-- Injection 800 mg Intravenous Ibuprofen In Group A

Main outcome variables

Curative Success(change of visual analogue scale till at least 3 score) ,Drug Side Effect

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180807040733N1**

Registration date: **2018-11-20, 1397/08/29**

Registration timing: **retrospective**

Last update: **2018-11-20, 1397/08/29**

Update count: **0**

Registration date

2018-11-20, 1397/08/29

Registrant information

Name

Khaghan Mohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3449 3136

Email address

drkhaghanmohammadi@sbm.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2018-01-30, 1396/11/10

Actual recruitment start date

2016-10-01, 1395/07/10

Actual recruitment end date

2018-01-30, 1396/11/10

Trial completion date

2018-01-30, 1396/11/10

Scientific title

Efficacy measurement of Intravenous Ibuprofen versus Intravenous Ketorolac in Patient Renal Colic Admittend in Emergency Department

Public title

Efficacy measurement of Intravenous Ibuprofen versus Intravenous Ketorolac in Patient Renal Colic Admittend in Emergency Department

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Every Adults with Renal Colic Diagnosis Age:Between 18 to 65 years old

Exclusion criteria:

Having Allergy to Ketorolac & Ibuprofen Noncooperation to Determine Severity Of Pain by VAS Pregnancy Having background of Heart disease & Hypertention disease Advanced Systemic disease, Malignancy,& Chronic Hepatic disease Psychiatric & Neurologic disease Use of NSAID at 6 hours ago

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **240**

Actual sample size reached: **240**

Randomization (investigator's opinion)

Randomized

Randomization description

Block Random Method Has Used In This Research. By A Professional Person Guidance In Random Blocks In 6 Size Was Planned By A Professional Person Guidance In Clinical Trial Study Methodology .Therefore 40 Prepared Blocks Was Specified According to This Method Patients Were Divided Into Two Groups Threatened By Ibuprofen(group A) & Threatened By Ketorolac (group B)

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, Researcher, Injector Nurse & Data Collecting liable have been Blind In This Research. The preparation of drug package was done by an individual who did not have any role in the research process at all, 30 mg of Ketorolac was poured into 100ml of normal saline & 800mg of Ibuprofen was poured in 100ml of another normal saline and placed in two group A & B and prepared For injection. From here on, a Nurse injector who was a person other than the person preparing the package , without any information on the contents of the pack , it only injected serum containing randomized into groups based on grouping alone , patients , with Full Justification for their treatment , after completing informed consent about participation in the research, Without any information about the type of drug , they were interviewed by the researcher after the end of injection at 15, 30, & 60 minutes. The main investigator on the type of injected drug was blind and unaware, This information was collected and evaluated based on the checklist. Actually, except for the package-maker who had no role in the research process, the rest of the group

was kept blind until the last stage.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

7th Floor, Bldg No. 2, Shahid Beheshti University Medical School, Arabi St, Velenjak Ave, Tehran Town

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2016-09-27, 1395/07/06

Ethics committee reference number

IR.SBMU.MSP.REC.1395.251

Health conditions studied

1

Description of health condition studied

Renal Colic

ICD-10 code

N20

ICD-10 code description

Calculus of kidney and ureter

Primary outcomes

1

Description

Curative Success (change of visual analogue scale till at least 3 score)

Timepoint

Incipience of Study , 15th minute, 30th, 60th

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohadaie Tajrish Hospital

Full name of responsible person

Khaghan Mohammadi

Street address

Shohadaie Tajrish Hospital, Shahrday
Ave, Tajrish, Tehran Town

City

Tehran

Province

Tehran

Postal code

1989934148

Phone

+98 21 25719

Fax

+98 21 2291 8001

Email

shohada@sbmu.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Prof Afshin Zarghi Vice--Chancellor In Reseach Affairs
of Shahid Beheshti Univercity

Street address

BldgNo.2, Shahid Beheshti Univercity , Arabi st,
Velenjak Ave, Tehran Town

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 2243 9781

Fax

+98 21 2243 9981

Email

Mpajouhesh@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Khaghan Mohammadi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Emergency Medicine

Street address

NO.13, Shahid Frotani Alley, Dekhoda St, Motahhari
Ave, Karaj Town

City

Karaj

Province

Alborz

Postal code

۳۱۴۵۹۵۴۹۱۸

Phone

+98 26 3449 3136

Fax

Email

drkhaghanmohammadi@sbmu.ac.ir

Person responsible for scientific inquiries

Contact

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Shahid Beheshti University of Medical Sciences

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+98 26 3449 3136

Fax**Email**

drkhaghanmohammadi@sbmu.ac.ir

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Final result of reaserch will be published as articl in the Emergency medicinemagazine of the Medical academy of Shahid Beheshty Univercity.

When the data will become available and for how long

This article will be published in the last thre months of 1397 & thence it will be available.

To whom data/document is available

Generally all researchers, specially Emergency medicine phisitions ,Urologists , chemists, students & also pharmaceutic companies can access issues of this research with observation of respective protocol.

Under which criteria data/document could be used

The stady data,s access is passible by getting permission of guidance prof &councillar & accurate observation of principle committec rules &my coordination to ward research &similar studies & check& contrast its results with related studies.

From where data/document is obtainable

You must to refer to prof Saeed Safari master of Emergency medicine of Shahid Beheshty Univercity&my councillor &statistics prof who has complete authority in terms of this issue to receive data &documentsof this research.He presents at Shohadaye Tajrish Hospital on tuesdays & at the research office of the medical school of the medical science academy of Shahid Beheshty Univercity the rest of week.phone number prof safari is 09128251535 , Email address is safari266@gmail.com

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

One who want to access this research,s data has to send his/her request to prof safari ,s e-mail address transpicuously & at least after time process 2 weeks can receivethis study,s data with prof,s agreement & approval. Email address is :safari266@gmail.com

Comments