# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 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)

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**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 Adalts with Renal Colic Diagnosis Age:Between 18 to 65 years old

**Exclusion criteria:**

Having Alergy to Ketorolac & Ibuprofen Noncooperation to Determine Severity Of Pain by VAS Peregnancy Having background of Heart disease & Hypertention disease Advanced Systemic disease, Malignancy,& Chronic Hepatic disease Psychiatric & Noroulogic 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 Metod Hase Used In This Reasearch. By A Proffesional Person Guidence In Random Blocks In 6 Size Was Planed By A Proffesional Person Guidence In Clinical Traial Study Metodology .Therefore 40 Prepared Blocks Was Specified According to This Method Pationts Were Divided Into Two Groups Threated By Ibuprofen(group A) & Threated By Ketorolac (group B)

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Participats, Reasercher, Injector Nurse & Data Collecting liable have been Blind In This Reaserch. The preparation of drug pakage was done by an individual who did not have any role inthe 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 pakage ,without any information on the contents of the pack , it only injected serum containing randomized into roups based on grouping alone , patients ,with Full Justification for theirtreatment , 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 at15,30,&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 reseach 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 commitee of Shahid Beheshti University of Medical Sciences

**Street address**

7thFloor,BldgNo.2,Shahid Beheshti Univercity Medical School, Arabi St,Velenjak Ave,Tehran Town

**City**

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**Province**

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**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 atleast 3 score)

**Timepoint**

Incipience of Stady , 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
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## Sponsors / Funding sources

**1**

**Sponsor**
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Shahid Beheshti University of Medical Sciences
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**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**
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**Position**
Resident
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## 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 phisitians ,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
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