

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 2026

### The comparison of Apotel (intravenous acetaminophen) with intravenous morphine in patients with acute renal colic

#### Protocol summary

##### Summary

Study objective: To evaluate the clinical efficacy of intravenous acetaminophen in lowering the dose of morphine in renal colic in Imam Reza (AS) Educational-Therapeutic Center of Tabriz University of Medical Sciences; Design of study: randomized, single blind, not-placebo controlled, single center trial; Inclusion criteria: patients 18-50 years old; known case of kidney stone. Exclusion criteria: using any drug for pain prior to attendance; allergy to the administered medications; history of opioid dependence; hypertension; fever and chills ; pregnancy and pain intolerance during the first 35 min of drug administration; Sample size: 100 divided in Two Groups Including intravenous 1 gram acetaminophen with Low Dose Morphine in Intervention Group vs. Intravenous 1mg/kg of morphine in control group; Duration of Intervention: 35 minutes; The effect of two drugs is evaluated based on pain intensity VAS system in minutes 0, 1, 5, 10, 15, 25 and 35 after Administration.

#### General information

##### Acronym

rss

##### IRCT registration information

IRCT registration number: **IRCT2013071411555N1**

Registration date: **2014-05-17, 1393/02/27**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2014-05-17, 1393/02/27

##### Registrant information

###### Name

Hamidreza Mortezaeigi

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1335 2078

##### Email address

mortezaabaghih@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tabriz University of Medical Sciences

##### Expected recruitment start date

2013-07-23, 1392/05/01

##### Expected recruitment end date

2014-01-21, 1392/11/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The comparison of Apotel (intravenous acetaminophen) with intravenous morphine in patients with acute renal colic

##### Public title

Evaluation of the effect of intravenous acetaminophen in lowering the dose of morphine in renal colic

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: patients 18-50 years old; known case of kidney stone. Exclusion criteria: using any drug for pain prior to attendance; allergy to the administered medications; history of opioid dependence; hypertension; fever and chills ; pregnancy and pain intolerance during the first 35 min of drug administration; pain intolerance

during the first 35 min of drug administration.

### Age

From **18 years** old to **50 years** old

### Gender

Both

### Phase

2-3

### Groups that have been masked

*No information*

### Sample size

Target sample size: **100**

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Single blinded

### Blinding description

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

The Ethics Committee of Tabriz University of Medical Sciences

##### Street address

Tabriz University, Medical Sciences Building

##### City

Tabriz

##### Postal code

##### Approval date

2013-06-12, 1392/03/22

##### Ethics committee reference number

9243

## Health conditions studied

### 1

#### Description of health condition studied

renal colic

#### ICD-10 code

n20,n21,n2

#### ICD-10 code description

Calculus of kidney and ureter which can cause colicky pain

## Primary outcomes

### 1

#### Description

pain severity

#### Timepoint

0, 1, 5, 10, 15, 25 and 35 min after drug administered

#### Method of measurement

visual analogue scale

## Secondary outcomes

### 1

#### Description

probable complications

#### Timepoint

during procedure until 1 week after discharge

#### Method of measurement

according to history and physical examination

## Intervention groups

### 1

#### Description

In intervention group, which the sample will be selected randomly out of 100 patients admitted with acute renal colic, 1 gram of Intravenous Acetaminophen (Aptel) combined with a low dose of Morphine will be administered.

#### Category

Treatment - Drugs

### 2

#### Description

In Control group, which will be selected randomly from the population of 100 patients admitted with acute renal colic, morphine will be administered intravenously with the dose of 0.1 mg/kg.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Emergency Department of Imam Reza (AS) Educational-Therapeutic Centre

##### Full name of responsible person

##### Street address

##### City

Tabriz

## Sponsors / Funding sources

### 1

#### Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr Hamidreza Morteza Beigi

**Street address**

Emergency department of Imam Reza (AS)  
Educational-Therapeutic Centre

**City**

Tabriz

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Tabriz 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**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr Hamidreza Morteza Beigi

**Position**

Specialty-assitant professor

**Other areas of specialty/work**

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Golgasht Street, Imam Reza Hospital

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**Full name of responsible person**

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**Position**

**Other areas of specialty/work**

**Street address**

**City**

**Postal code**

**Phone**

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**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*