# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Jul 2026

## Comparison of paracetamol versus ketorolac on decreasing of low back pain: clinical trial

## Protocol summary

**Summary**

Title: Comparison of paracetamol versus ketorolac on decreasing of low back pain. Purposes: Appointment of the severity of the pain on the basis of VAS in patients with chief complaint of low back pain before treatment, 10 and 20 and 30 minutes and 24 hours after treatment in apotel, intravenous keterolac group. Design, method and interventions:Among the all patients with chief complaint of low back pain, 180 patients will be selected randomly. Sample will be divided in two groups randomly. In first group after diagnosis, 1 gram intravenous acetaminophen will be soluted in 100 cc normal saline and will be infused in 10 minutes. In the second group, a ketorolac ampule in order to stimulation will be soluted in 100 cc normal saline and will be infused in 10 minutes. Inclusion criteria: Patients between 18 up to 65 years old with chief complaint of low back pain. Exclusion criteria: Patients who have contraindication for use of NSAID; use of opioid in last six hours; patients with red flag symptoms such as neurological abnormalities or fever; patients with suggestive signs for discopathy in MRI.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT201404127327N1**
Registration date: **2015-02-01, 1393/11/12**
Registration timing: **retrospective**

Last update:
Update count: **0**

**Registration date**

2015-02-01, 1393/11/12

**Registrant information**

**Name**

Samad Shams Vahdati

**Name of organization / entity**

Tabriz University of Medical Scinces

**Country**

Iran (Islamic Republic of)

**Phone**

+98 41 1658 1401

**Email address**

shams@tbzmed.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

Tabriz University of Medical Sciences

**Expected recruitment start date**

2014-06-05, 1393/03/15

**Expected recruitment end date**

2014-12-01, 1393/09/10

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of paracetamol versus ketorolac on decreasing of low back pain: clinical trial

**Public title**

Comparison of paracetamol versus ketorolac on decreasing of low back pain: clinical trial

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: Patients between 18 up to 65 years old with chief complaint of low back pain. Exclusion criteria: Patients who have contraindication for use of NSAID; use of opioid in last six hours; patients with red flag symptoms such as neurological abnormalities or fever; patients with suggestive signs for discopathy in MRI.

**Age**
From **18 years** old to **65 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)**
Double blinded
**Blinding description**
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Local Ethics Committee,Tabriz University of medical science
**Street address**
Central Building Number 2, Tabriz University of Medical Sciences, Golgasht Street, Tabriz, Iran
**City**
Tabriz
**Postal code**
**Approval date**
2014-02-24, 1392/12/05
**Ethics committee reference number**
5/4/10985

## Health conditions studied

### 1

**Description of health condition studied**
Low back paine
**ICD-10 code**
M54.9
**ICD-10 code description**
Dorsalgia, unspecified

## Primary outcomes

### 1

**Description**
Pain severity
**Timepoint**
In intrance, after 10, 20, 30 minute and 24 hour later
**Method of measurement**
Visual Analoge score

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: After confirming diagnosis, 1 gram paracetamol will be soluted in 100 cc normal saline and will be infused in 10 minute. Drug name: Intravenous Paracetamol Chemical compound: Acetaminophen Dose: 1 gram acetaminophen in 100 cc normal saline
**Category**
Treatment - Drugs

### 2

**Description**
Control group: one ampule of ketorolac in order to stimulation will be soluted in 100 cc normal saline and will be infused in 10 minutes. Drug name: Ketorolac Chemical compound: Ketorolac Dose: one ampule of ketorolac with dosage of 30 milligram per milliter.
**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Imam Reza Hospital
**Full name of responsible person**
Dr. Samad Shams Vahdati
**Street address**
Gholghasht street
**City**
Tabriz

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Student Research Commitee, Tabriz University of Medical Science
**Full name of responsible person**
Dr. Somaieh Halaj Nezhadi
**Street address**
Education Development Center, Daneshghah street,
**City**
Tabriz

**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Student Research Commitee, Tabriz University of Medical Science
**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. Samad Shams Vahdati
**Position**
Assistant Professor of Emergency Medicine
**Other areas of specialty/work**
**Street address**
Imam Reza Hospital, Gholghasht street
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**Postal code**
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+98 41 1335 2078
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shams@tbzmed.ac; irsshamsv@yahoo.com
**Web page address**

## Person responsible for scientific inquiries

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**Full name of responsible person**
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**Position**
Assistant professor of emergency medicine
**Other areas of specialty/work**
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**Fax**
**Email**
shams@tbzmed.ac.ir; sshamsv@yahoo.com
**Web page address**

## Person responsible for updating data

**Contact**

## 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*