# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 2026

## A clinical trial to comparison of the Injury Severity Score (ISS) between cannabis, opium, and benzodiazepine consumption and healthy individuals in patients with head trauma

## Protocol summary

**Summary**

Objective: Effectiveness of the Injury Severity Score (ISS) between cannabis, opium, and benzodiazepine consumption and healthy individuals in patients with head trauma. Design: A not blinded, block randomized clinical trial. Study population: Patients with head trauma are referring to Shahid Hashemi Nezhad Hospital in Mashhad. Inclusion criteria: Patients with head trauma are referring to Shahid Hashemi Nezhad Hospital in Mashhad; Glasgow Coma Scale (GCS) between 9 to 13. Exclusion criteria: Patients who not consent to measure the specific substance urinary levels; patient with anuria; patient with shock. Sample size: 75 cases. Study intervention: Evaluation of cannabis, opium, and benzodiazepine urinary levels with immunochromatography and the Injury Severity Score (ISS) with questionnaire in healthy individuals and cannabis, opium, and benzodiazepine consumption with head trauma. Study outcome: Evaluation and comparison of the Injury Severity Score (ISS) between cannabis, opium, and benzodiazepine consumption and healthy individuals in patients with head trauma.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2016100514872N3**
Registration date: **2016-11-06, 1395/08/16**
Registration timing: **prospective**

Last update:
Update count: **0**

**Registration date**

2016-11-06, 1395/08/16

**Registrant information**

**Name**

Mohammad Davood Sharifi

**Name of organization / entity**

Mashhad University of Medical Sciences

**Country**

Iran (Islamic Republic of)

**Phone**

+98 51 3852 5312

**Email address**

sharifimd@mums.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

Vice Chancellor for Research, Mashhad University of Medical Sciences

**Expected recruitment start date**

2016-11-21, 1395/09/01

**Expected recruitment end date**

2018-06-05, 1397/03/15

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

A clinical trial to comparison of the Injury Severity Score (ISS) between cannabis, opium, and benzodiazepine consumption and healthy individuals in patients with head trauma

**Public title**

The Injury Severity Score (ISS) in patients with head trauma

**Purpose**

Supportive

**Inclusion/Exclusion criteria**

Inclusion criteria: Patients with head trauma are referring to Shahid Hashemi Nezhad Hospital in Mashhad; Glasgow Coma Scale (GCS) between 9 to 13. Exclusion criteria: Patients who not consent to measure the specific substance urinary levels; patient with anuria; patient with shock.

**Age**

No age limit

**Gender**

Both

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **75**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

**Blinding (investigator's opinion)**

Not 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**

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

**City**

Mashhad

**Postal code**

**Approval date**

2015-02-22, 1393/12/03

**Ethics committee reference number**

IR.MUMS.REC.1393.954

## Health conditions studied

### 1

**Description of health condition studied**

Patients with head trauma

**ICD-10 code**

S09.9

**ICD-10 code description**

Unspecified injury of head

## Primary outcomes

### 1

**Description**

Cannabis, opium, and benzodiazepine urinary levels

**Timepoint**

After refer to hospital

**Method of measurement**

Immunochromatography

## Secondary outcomes

### 1

**Description**

Injury Severity Score (ISS)

**Timepoint**

After refer to hospital

**Method of measurement**

Questionnaire

## Intervention groups

### 1

**Description**

Control group: Evaluation of cannabis, opium, and benzodiazepine urinary levels with immunochromatography and the Injury Severity Score (ISS) with questionnaire in healthy individuals with head trauma.

**Category**

Diagnosis

### 2

**Description**

Intervention group: Evaluation of cannabis, opium, and benzodiazepine urinary levels with immunochromatography and the Injury Severity Score (ISS) with questionnaire in cannabis, opium, and benzodiazepine consumption with head trauma.

**Category**

Diagnosis

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Shahid Hashemi Nezhad Hospital

**Full name of responsible person**

Elham Masomzade

**Street address**

Shahid Hashemi Nezhad Hospital, Tolab, Shahid Mofateh Avenue, end of Abooreihan Boulevard

**City**

Mashhad

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Vice Chancellor for Research, Mashhad University of Medical Sciences

**Full name of responsible person**

Mohsen Tafaghodi

**Street address**

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, 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**

Vice Chancellor for Research, 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**

Vawoud Sharifi

**Position**

Emergency Medicine

**Other areas of specialty/work**

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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)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*