

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 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

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Iran (Islamic Republic of)

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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

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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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