

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

Evaluation of the sedative effect of sublingual lorazepam versus placebo in patients who are candidate for endoscopy: a double blind randomized clinical trial

Protocol summary

Summary

Objectives: To assess the sedative effect of sublingual lorazepam versus placebo in patients who are candidate for endoscopy. Design: a double blind randomized clinical trial. Setting and conduct: The eligible patients who are candidate for endoscopy and will refer to Shahid Beheshti Hospital during the study period will be enrolled into the trial. Inclusion criteria: candidate for endoscopy; age of 18 to 55 years. Exclusion criteria: cardiopulmonary disease; neuropsychological disorders; sensitivity to lorazepam; body mass index above 30. Intervention group: sublingual tablet lorazepam 2 mg single dose half hour before endoscopy. Control group: placebo single dose half hour before endoscopy Primary outcome: sedative effect of drug half hour after treatment through physical examination. Randomization: The patients will be randomly assigned to intervention and control groups using block randomization. Blinding: Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Therefore, the trial will be run as double blind.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201611039014N130**
Registration date: **2016-11-05, 1395/08/15**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-11-05, 1395/08/15

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan
University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan
University of Medical Sciences

Expected recruitment start date

2016-11-21, 1395/09/01

Expected recruitment end date

2017-11-21, 1396/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the sedative effect of sublingual lorazepam versus placebo in patients who are candidate for endoscopy: a double blind randomized clinical trial

Public title

Evaluation of the sedative effect of sublingual lorazepam versus placebo in patients who are candidate for endoscopy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: candidate for endoscopy; age of 18 to 55 years. Exclusion criteria: cardiopulmonary disease; neuropsychological disorders; sensitivity to lorazepam; body mass index above 30.

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **114**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Randomization: The patients will be randomly assigned to intervention and control groups using block randomization. Blinding: Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Therefore, the trial will be run as double blind.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research the Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Postal code

6517838695

Approval date

2016-10-29, 1395/08/08

Ethics committee reference number

IR.UMSHA.REC.1395.347

Health conditions studied

1

Description of health condition studied

candidate for endoscopy

ICD-10 code

Y61.4

ICD-10 code description

During endoscopic examination

Primary outcomes

1

Description

sedative effect of drug

Timepoint

half hour after treatment

Method of measurement

through physical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: sublingual tablet lorazepam 2 mg single dose half hour before endoscopy.

Category

Treatment - Drugs

2

Description

Control group: placebo single dose half hour before endoscopy

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Zohreh Seifi

Street address

Shahid Beheshti Hospital, Eram Ave.

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research the Technology,
Hamadan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

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 the Technology, Hamadan
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

Shahid Beheshti Hospital

Full name of responsible person

Zohreh Seifi

Position

Medical Student

Other areas of specialty/work

Street address

Shahid Beheshti Hospital, Eram Ave.

City

Hamadan

Postal code

Phone

+98 81 3838 0283

Fax

Email

zseifi861372@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti Hospital

Full name of responsible person

Dr Maryam Hasan Zarini

Position

Internist

Other areas of specialty/work

Street address

Shahid Beheshti Hospital, Eram Ave.

City

Hamadan

Postal code

Phone

+98 81 3838 0283

Fax

Email

mhzarrini@sums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Department of Epidemiology

Full name of responsible person

Dr Jalal Poorolajal

Position

Associate Professor

Other areas of specialty/work

Street address

School of Public Health, Hamadan University of
Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0090

Fax

Email

poorolajal@umsha.ac.ir

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