Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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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

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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

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Position

Medical Student

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Department of Epidemiology

Full name of responsible person

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Associate Professor

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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