

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparing the relaxation effect of diazepam of oral administration of single and divided dose in Patients with limited mouth opening origin of masticatory muscles

#### Protocol summary

##### Summary

The patients with limitation in mouth opening have some problems in eating and speaking. Therefore, getting impressions for their oral appliance therapy is often impossible and the dentists use other treatment to reach the appropriate mouth opening. Benzodiazepines are a group of drugs which use as muscle relaxants. However Diazepam is commonly used for muscle relaxing by the central effect, but there is no certain research on its dosage and mode of administration for the muscle of mastication. Diazepam has a high kinetic lifetime, but its effect on the CNS is low due to high lipophilic condition (It quickly enters to CNS and exits). So if we increase the number of doses, its effectiveness may be improved. The aim of this study is a comparison of muscle relaxation in patients with limitation in mouth opening that use single or divided dose of Diazepam. 48 patients with limitation in mouth opening in the range of 8-10 mm with the origin of masticatory muscles are assigned to three groups randomly. The first group used up a dose of 10 mg, the second group used up two dose of 5 mg and the third group used up four dose of 2.5 mg Diazepam daily. The rage of mouth opening (from incisal edge of the right centrals) will be measured in millimeter and the pain during the mouth opening will be scaled on the VAS before and after using the drugs in the third, fifth and seventh days.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017032933167N1**  
Registration date: **2017-05-15, 1396/02/25**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-05-15, 1396/02/25

##### Registrant information

###### Name

Neda Jarahi

###### Name of organization / entity

Mashhad University of Medical Science(MUMS)

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3882 9501

###### Email address

jarrahin921@mums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice Chancellor Of Research, Mashhad University of Medical Science

##### Expected recruitment start date

2017-04-30, 1396/02/10

##### Expected recruitment end date

2018-05-31, 1397/03/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparing the relaxation effect of diazepam of oral administration of single and divided dose in Patients with limited mouth opening origin of masticatory muscles

##### Public title

Comparing the relaxation effect of diazepam of oral

administration of single and divided dose in Patients with limited mouth opening origin of masticatory muscles

### **Purpose**

Treatment

### **Inclusion/Exclusion criteria**

Exclusion criteria: Pregnancy; Breastfeeding; using Drugs have interactions with diazepam (such as cimetidine, Amvprazol, phenytoin, erythromycin and fungicides); Liver and kidney disfunctions (with tests SGOT, SGPT, ALP, Bun-Creatinine); alcoholism; glaucoma; severe difficulty breathing; Sleep Apnea; Epilepsy; Consumers of other benzodiazepines; other muscle relaxants and anti-inflammatory drugs; close lock; the joint disorders; chronic slow mandible; patients with submucosal fibrosis; patients radiotherapy; Sensitivity to diazepam Inclusion criteria: Patients with limitation in mouth opening by the source of masticatory muscle

### **Age**

From **16 years** old to **60 years** old

### **Gender**

Both

### **Phase**

N/A

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **48**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Single 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 Dental Faculty

##### **Street address**

Opposite Melat Park. Mashhad

##### **City**

Mashhad

##### **Postal code**

#### **Approval date**

2017-03-15, 1395/12/25

#### **Ethics committee reference number**

IR.mums.sd.REC.1394.213

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

limitation of mouth opening due to masticatory muscles

#### **ICD-10 code**

XIII

#### **ICD-10 code description**

Diseases of the musculoskeletal system and connective tissue

## **Primary outcomes**

### **1**

#### **Description**

range of mouth opening

#### **Timepoint**

before Intervention and in 3,5 and 7 days after Intervention

#### **Method of measurement**

the distance between incisal edge of two right centrals in millimeter

## **Secondary outcomes**

### **1**

#### **Description**

pain through opening

#### **Timepoint**

before Intervention and in 3,5 and 7 days after Intervention

#### **Method of measurement**

VAS(visual analog scale)

### **2**

#### **Description**

drug complications

#### **Timepoint**

before Intervention and in 3,5 and 7 days after Intervention

#### **Method of measurement**

patient's discription

## **Intervention groups**

### **1**

#### **Description**

oral diazepam 10 mg/ 1 tab daily maximum for 1 week

#### **Category**

Treatment - Drugs

### **2**

#### **Description**

oral diazepam 5 mg/ 2 tab daily maximum for 1 week

#### **Category**

Treatment - Drugs

### 3

#### Description

oral diazepam 2.5 mg/ 4 tab daily maximum for 1 week

#### Category

Treatment - Drugs

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

Dental Faculty of Mashhad

###### Full name of responsible person

Neda Jarahi

###### Street address

###### City

Mashhad

### Sponsors / Funding sources

#### 1

##### Sponsor

###### Name of organization / entity

Vice Chancellor Of Research, Mashhad University of  
Medical Science

###### Full name of responsible person

Azam Sadat Madani

###### Street address

Vice Chancellor Of Research, Mashhad University of  
Medical Science

###### 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 Of Research, Mashhad 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

Dental Faculty of Mashhad University

###### Full name of responsible person

Neda Jarahi

##### Position

Prosthodontics Resident

##### Other areas of specialty/work

##### Street address

Opposit Mellat park,Vakil abad boulevard,

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jarrahin921@mums.ac.ir

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### Person responsible for scientific inquiries

##### Contact

###### Name of organization / entity

Dental Faculty of Mashhad

###### Full name of responsible person

Azam Sadat Madani

###### Position

Professor

###### Other areas of specialty/work

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### Person responsible for updating data

##### Contact

###### Name of organization / entity

Mashhad University of Medical Science

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Neda Jarahi

###### Position

Resident of Prosthesis

###### 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*