

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 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)

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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

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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