

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Comparison of Plaque Control Efficacy Of Chewing Gum Containing Ethylenediaminetetraaceticacid(EDTA),methylsulfonylmethane(MSM) and Xylitol with Chlorehexidine Mouthrinse

#### Protocol summary

##### Summary

This study will be done with purpose of comparison of plaque control efficacy of chewing gum containing ethylenediaminetetraaceticacid, methyl sulfonyl methane and xylitol with chlorehexidine mouthrinse. For this purpose we choose 24 patients who referred to periodontics clinic of dental college of Hamedan University of Medical Sciences. These patients must have over 40% of O'leary plaque index and have no systemic diseases. This study is an interventional and cross-over designed. For each patient a SRP will be done and O'leary plaque index, gingival index and sulcus bleeding index will be recorded. Patients will be divided into two groups randomly. one group will receive EDTA/MSM/Xylitol chewing gum and another group will receive chlorehexidine mouthrinse. After 14 days all 3 Indexes will be recorded again and a tooth polishing will be done for each patient. Groups' intervention will be changed and after another 14 days and all 3 Indexes will be recorded again and a tooth polishing will be done for each patient.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017070234849N1**

Registration date: **2017-08-28, 1396/06/06**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2017-08-28, 1396/06/06

##### Registrant information

Name

Morteza Shakhs Niaee

##### Name of organization / entity

Hamedan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 3252 6200

##### Email address

dr.niaee@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for research and innovation of Hamedan University of Medical Sciences

##### Expected recruitment start date

2017-09-23, 1396/07/01

##### Expected recruitment end date

2017-11-22, 1396/09/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of Plaque Control Efficacy Of Chewing Gum Containing Ethylenediaminetetraaceticacid(EDTA),methylsulfonylmethane(MSM) and Xylitol with Chlorehexidine Mouthrinse

##### Public title

Considering the effect of a new chewing gum in preventing dental plaque formation

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

patients must have over 40% of o'leary plaque index.

patients must have no systemic disease.

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: 24

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Crossover

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Hamedan University of Medical Sciences

**Street address**

Hamedan University of Medical Sciences, Ayatollah kashani boulevard, khaje rashid cross

**City**

Hamedan

**Postal code****Approval date**

2017-07-08, 1396/04/17

**Ethics committee reference number**

IR.UMSHA.REC.1396.306

**Health conditions studied****1****Description of health condition studied**

gingivitis and periodontitis

**ICD-10 code**

k05

**ICD-10 code description**

gingivitis and periodontal diseases

**Primary outcomes****1****Description**

O'leary plaque index

**Timepoint**

14 days

**Method of measurement**

Visionary scale using disclosing agents

**2****Description**

Gingival index

**Timepoint**

14 days

**Method of measurement**

Visionary scale of gingival inflammation

**3****Description**

sulcus bleeding index

**Timepoint**

14 days

**Method of measurement**

Visionary scale of sulcus bleeding

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: using EDTA/MSM/Xylitol chewing gum, twice a day, each time one piece of 2.7 gram gum, chewing for 10 minutes

**Category**

Prevention

**2****Description**

Control Group: using 0.12% chlorhexidine mouthrinse, twice a day, each time 10 ml, rinsing for 30 seconds

**Category**

Prevention

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Dentistry College of Hamedan University of Medical Sciences

**Full name of responsible person**

morteza shakhs niaee

**Street address**

Hamedan University of Medical Sciences, Ayatollah Kashani boulevard, Khaje Rashid cross

**City**  
Hamedan

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**  
Vice Chancellor for research and innovation of  
Hamedan University of Medical Sciences

**Full name of responsible person**  
dr morad hedayati panah

**Street address**  
Hamedan University of Medical Sciences, Ayatollah  
Kashani boulevard, Khaje Rashid cross

**City**  
Hamedan

### 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 and innovation of Hamedan  
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**  
Hamedan University of Medical Sciences

**Full name of responsible person**  
Morteza Shakhs Niaee

**Position**  
Dentistry student

**Other areas of specialty/work**

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## Person responsible for scientific

## inquiries

### Contact

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PHD

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## Person responsible for updating data

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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*