

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 2026

### Evaluation of the effect of fluoride containing 0.12% chlorhexidine on dental plaque, gingival and stain index in the patients

#### Protocol summary

##### Summary

The aim of the study is to assess the effect of fluoride containing chlorhexidine 0.12% on dental plaque index (PI), gingival and stain index (GI, SI) in patients referred to Periodontal department, School of dentistry, Golestan University of Medical Sciences. This study is a randomized, parallel, double blind study. The patients are 50-18 years old. Patients are randomly assigned into two groups. In one group chlorhexidine 0.12% (laboratories world of health, Iran) is prescribed and another group are asked to use chlorhexidine 0.12% + Sodium fluoride 0.05% (EMAD Pharma, Iran), twice daily for 2 weeks and refrain from eating for half an hour. PI, GI and SI are recorded by a blinded clinician before and after the use of mouthrinses. Data are analyzed using SPSS16.

#### General information

##### Acronym

Evaluation of the effect of fluoride containing 0.12% chlorhexidine

##### IRCT registration information

IRCT registration number: **IRCT2016110630744N1**  
Registration date: **2017-04-05, 1396/01/16**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-04-05, 1396/01/16

##### Registrant information

###### Name

Elham Fakhari

###### Name of organization / entity

Golestan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 11 3227 2253

###### Email address

dr.fakhari@goums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research, Golestan university of medical sciences

##### Expected recruitment start date

2016-11-20, 1395/08/30

##### Expected recruitment end date

2017-05-31, 1396/03/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the effect of fluoride containing 0.12% chlorhexidine on dental plaque, gingival and stain index in the patients

##### Public title

The effect of fluoride containing chlorhexidine on the gingival health

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

inclusion criteria: presence of 20 teeth except wisdom teeth in the mouth, pocket depth <5 mm, Attachment loss <2 mm. exclusion criteria: 1. pathological lesions of the oral mucosa 2. use of mouthwash in a study last month 3- systemic disease effective on periodontal condition 4-history of allergy to chlorhexidine 5-partial denture or ortodontic appliance

##### Age

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: 40

**Randomization (investigator's opinion)**

Randomized

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

Double blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features**

Random with random numbers table

**Secondary Ids****1****Registry name**

ندارد

**Secondary trial Id**

ندارد

**Registration date**

empty

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

Golestan University of Medical Sciences

**Street address**

in front of Edalat97, Gorgan dentistry school, Gorgan,  
post code:49169-53363

**City**

Gorgan

**Postal code**

49169-53363

**Approval date**

2016-08-22, 1395/06/01

**Ethics committee reference number**

IR.goums.REC.1395.145

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

dental plaque,gingival inflammation,dental color change

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

gingival inflammation

**Timepoint**

first day and seventh day and The fifteenth day of  
intervention

**Method of measurement**

gingival index(loe&silness)

**2****Description**

dental plaque

**Timepoint**

first day and seventh day and The fifteenth day of  
intervention

**Method of measurement**

plaqe index(loe&silness)

**3****Description**

dental color change

**Timepoint**

first day and seventh day and The fifteenth day of  
intervention

**Method of measurement**

color change index DI,Brecx et al

**Secondary outcomes**

empty

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

intervention group: mouthwash chlorhexidine 0.12% +  
sodium fluoride0.05%(EMAD pharma,Iran) twice daily for  
2 weeks and refrain from eating for half an hour

**Category**

Treatment - Drugs

**2****Description**

control Group: mouthwash chlorhexidine 0.12%  
(laboratories world of health, Iran) twice daily for 2  
weeks and refrain from eating for half an hour

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center**

Name of recruitment center

periodontal department, School of dentistry, Golestan  
University of Medical Sciences

**Full name of responsible person**

Dr Elham Fakhari

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in front of Edalat97, Gorgan, postcode:49169-53363

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**Web page address**

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## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

vice chancellor for research of Golestan University of  
Medical Sciences

**Full name of responsible person**

Dr Mohamad Hossein Taziki

**Street address**

First shastkola, km 5 Gorgan

**City**

Gorgan

**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 of Golestan 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**

school of dentistry, Golestan university of medical  
science

**Full name of responsible person**

Dr Elham Fakhari

**Position**

assistant professor Periodontics

**Other areas of specialty/work**

**Street address**

gorgan-in front of Edalat 97-dentistry clinic of  
golestan university of medical science

**City**

gorgan

**Postal code**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

dentistry school of golestan university of medical  
science

**Full name of responsible person**

Dr Elham Fakhari

**Position**

Professor of Periodontics

**Other areas of specialty/work**

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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*