Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 chlorhexidine0.12% + 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)

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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 applience

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 plaqe,gingival inflamation,dental color change

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
gingival inflamation

Timepoint
first day and seventh day and The fifteenth day of intervention

Method of measurement
gingival index(loe&silness)

2

Description
dental plaqe

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

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

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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

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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 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
assisstant professor Periodontics

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