Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

A comparison of effect of Benzydamin Hcl 0.15% and Chlorhexidine 0.2% mouthwashes on the level of plaque formation, tooth staining and gingival bleeding index in patients that reffering to the Rafsanjan Dental School in 2015

Protocol summary

Summary

Dental plaque is associated with dental caries and periodontitis, but plaque formation is a normal processes that we don't prevent this formation. Mechanical plaque control methods is the best way to reduce of plaque, but due to the limitation of mechanical methods, chemical material are used to complete mechanical methods. Chlorhexidine(CHX) is one of the most effective materials in chemical plaque formation, but metallic taste and tooth discoloration are side effect of this material. Benzydamine mouth rinse has anti-bacterial, anti-pain and non-steroid anti-inflammatory properties. The purpose of this research was to compare anti-plaque, bleeding index and tooth discoloration in 0/2% Chlorhexidine and 0/15% Benzydamin mouth rinses. Materials and Methods: 56 patient with gingivitis and mild periodontitis have been studied and patient randomly were divided into two group(each group 28 patient). At first Bleeding Index(BI) & Plaque Index(PI) were recorded and scaling and root planning was performed, and in one group 0/2% Chlorhexidine mouth rinse and in other group 0/15% Benzydamine mouth rinse was prescribed to be used twice a day for 14 days. After two weeks BI & PI were recorded, intensity and extent of staining from 12 anterior tooth recorded. At the end of study polishing was performed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016010325819N1**
Registration date: **2016-06-14, 1395/03/25**
Registration timing: **na**
Last update:
Update count: **0**

Registration date

2016-06-14, 1395/03/25

Registrant information

Name
Somaye Salari Sedigh
Name of organization / entity
Rafsanjan Dental school
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Recruitment status

Not enough for processing

Funding source

Rafsanjan Dental school

Expected recruitment start date

2015-07-23, 1394/05/01

Expected recruitment end date

2015-04-21, 1394/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison of effect of Benzydamin Hcl 0.15% and Chlorhexidine 0.2% mouthwashes on the level of plaque formation, tooth staining and gingival bleeding index in patients that reffering to the Rafsanjan Dental School in 2015

Public title
Effect of benzydamine mouthwash on gingival indexes
Purpose
Diagnostic
Inclusion/Exclusion criteria
Inclusion criteria: patients with gingivitis and mild periodontitis; having at least 12 anterior teeth; not smokers patients; no staining in tooth; do not using removable denture; not using any drug.
Age
From **20 years** old to **45 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **56**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Rafsanjan University of Medical Sciences
Street address
Rafsanjan University of Medical Sciences, Imam Ali blvd.
City
Rafsanjan
Postal code
7717933777
Approval date
2016-01-10, 1394/10/20
Ethics committee reference number
IR.RUMS.REC.1394.173

Health conditions studied

1

Description of health condition studied
Mild periodontitis
ICD-10 code
K05
ICD-10 code description
Gingivitis and periodontal diseases

Primary outcomes

1

Description
Plaque index
Timepoint
Before intervention and two weeks later
Method of measurement
With disclosing agent

2

Description
Bleeding index
Timepoint
Before intervention and two weeks later
Method of measurement
Williams probe

3

Description
Tooth staining
Timepoint
Before and two weeks after intervention
Method of measurement
Lobein stain index

4

Description
Probing depth index
Timepoint
Before intervention and two weeks later
Method of measurement
With williams probe

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: benzydamine/15% twice in a day for 2 weeks
Category
Treatment - Other

2

Description
Control group: chlorhexidine /2% twice at dayfor 2 weeks
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Rafsanjan Dental school
Full name of responsible person
Mohsen Rastar
Street address
Rafsanjan Dental school, West Mofatteh blvd.
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Rafsanjan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research assistance of Rafsanjan University of Medical Sciences
Full name of responsible person
Dr. Hamid Hakimi
Street address
Rafsanjan University of Medical Sciences, Emam Ali blvd.r
City
Rafsanjan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research assistance of Rafsanjan 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

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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