

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 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

Country

Iran (Islamic Republic of)

Phone

+98 34 3428 0030

Email address

s_salarisedigh@rums.ac.ir

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.

City

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

Contact

Name of organization / entity

Rafsanjan Dental school

Full name of responsible person

Somaye Salari Sedigh

Position

Assistant professor

Other areas of specialty/work

Street address

Rafsanjan Dental school, West Mofatteh blvd.

City

Rafsanjan

Postal code

7716614618

Phone

+98 34 3428 0030

Fax

Email

ssalarisedigh@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Rafsanjan Dental school

Full name of responsible person

Somaye Salari Sedigh

Position

Assistant professor

Other areas of specialty/work

Street address

Rafsanjan Dental school, West Mofatteh blvd.

City

Rafsanjan

Postal code

7716614618

Phone

+98 34 3428 0030

Fax

Email

ssalarisedigh@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Rafsanjan Dental school

Full name of responsible person

Somaye Salari Sedigh

Position

Assitant professor

Other areas of specialty/work

Street address

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City

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Phone

+98 34 3428 0030

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Email

ssalarisedigh@gmail.com

Web page address

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