

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of the effect of fluoride mouthwash with chlorhexidine on gingivitis in 15 to 30 year olds individuals.

Protocol summary

Study aim

Determination and comparison of sodium fluoride mouthwash and chlorhexidine mouthwash on gingivitis

Design

Clinical trials with control group, with parallel groups, double-blind, randomized

Settings and conduct

100 patients with gingivitis referred to the periodontics department of Zahedan School of Dentistry, were divided randomly into two groups. After the clinical examination, plaque index and Gingival inflammation were recorded on specific charts. Each patient was given one of the mouthwashes according to his/her group. After two weeks, the plaque index and gingival inflammation was measured again and analyzed statistically.

Participants/Inclusion and exclusion criteria

Patients 15 to 30 years old with gingivitis; at least 20 permanent teeth without extensive restoration; non-use of partial dentures and orthodontic appliance; non-smoking; non-use of antibiotics and mouthwash in the last three months.

Intervention groups

Group 1: Use sodium fluoride mouthwash for two weeks
Group 2: Use of chlorhexidine mouthwash for two weeks

Main outcome variables

Dental plaque; Gingival bleeding

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180718040522N1**

Registration date: **2018-07-28, 1397/05/06**

Registration timing: **retrospective**

Last update: **2018-07-28, 1397/05/06**

Update count: **0**

Registration date

2018-07-28, 1397/05/06

Registrant information

Name

Masoud Bamedi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3342 9519

Email address

z@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-28, 1397/03/07

Expected recruitment end date

2018-06-28, 1397/04/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of fluoride mouthwash with chlorhexidine on gingivitis in 15 to 30 year olds individuals.

Public title

Comparison of the effect of two mouthwashes on gingivitis in 15 to 30 years old individuals.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Have at least 20 teeth without massive restoration

Exclusion criteria:

Use of partial denture Use of orthodontic appliances
Systemic diseases Periodontitis disease Tobacco use
Taking any antibiotic over the past three months Taking
any mouthwash over the past three months

Age

From **15 years** old to **30 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Using random block method, subjects will be categorized in one of the two examined groups. Randomly, numbers from one form of 1 to 10 are selected and written in sequence. We assign the numbers below 5 as AB and assign the upper 5 numbers to BA and based on the given number we categorize persons in either AB or BA group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The same mouthwashes are provided by the other person to the patients and so the patient, the therapist, and the researcher are unaware of the type of mouthwash used, and also the person who is analyzing the data is unaware of the kind of used mouthwash.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zahedan University of Medical Sciences

Street address

ZaUMS Main campus, Jenat Blvd., Zahedan, Sistan and Baluchestan, Iran

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Approval date

2018-05-27, 1397/03/06

Ethics committee reference number

IR. ZAUMS. REC.1397.101

Health conditions studied

1

Description of health condition studied

Gingival inflammation

ICD-10 code

K05.1

ICD-10 code description

Chronic gingivitis

Primary outcomes

1

Description

Dental plaque

Timepoint

Two weeks after use of mouthwash

Method of measurement

Plaque index (silness and loe plaque index)

2

Description

Gingival bleeding

Timepoint

Two weeks after use of mouthwash

Method of measurement

Evaluation of BOP by williams periodontal prob according to silness and loe index

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Use of 0.2% Chlorhexidine mouthwash for two weeks

Category

Treatment - Drugs

2

Description

Intervention group: Use of 0.05% sodium fluoride mouthwash for two weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Zahedan University of medical sciences

Full name of responsible person

Abdolghafour Pakseresht

Street address

College of dentistry , Eastern Azadegan St. , Zahedan

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9817699693

Phone

+98 54 3344 1814

Email

final047@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Dr. Nourmohammad Bakhshani

Street address

ZaUMS Main campus, Jenat Blvd., Zahedan

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Phone

+98 54 3342 5765

Email

nmbakhsha@Zaums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Zahedan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Abdolghafour Pakseresht

Position

Dentistry Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

Street address

College of dentistry, Eastern Azadegan st.

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9817699693

Phone

+98 54 3329 5715

Email

final047@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Masoud Bamedi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

College of dentistry , Eastern Azadegan St. , Zahedan

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9817699693

Phone

+98 54 3342 9519

Fax**Email**

z@zaums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Zahedan University of Medical Sciences

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Masoud Bamedi

Position

Assistant professor

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Dentistry

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Province

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Postal code

9817699693

Phone

+98 54 3342 9519

Fax

Email

z@zaums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available