

# 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**

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9817699693

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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

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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

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## 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

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## Person responsible for updating data

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**Position**

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**Latest degree**

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**Other areas of specialty/work**

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**Fax**

**Email**

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**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