

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

comparson of the effect of Chlorhexidine mouthwash and sodium fluoride mouthwash on gingival healing around stainless steel crown in primary teeth

Protocol summary

Study aim

Comparison of the effect of chlorhexidine mouthwash and sodium fluoride mouthwash on gum health after stainless steel crowns in primary teeth.

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 30 patients.

Settings and conduct

The study is conducted in the children's department of the dental clinic of Ilam University of Medical Sciences on children aged 6 to 12 years. 30 patients are divided into two equal groups. The amount of plaque index and gingival index around the decayed tooth is measured. chlorhexidine and sodium fluoride mouthwashes are applied twice a day for a week with an ear cleaner around the ssc cover done at the college. At the end, plaque index and gingival index are calculated.

Participants/Inclusion and exclusion criteria

log in : Children 6 to 12 years old At least 1 primery tooth needs ssc coating Failure to enter: Systemic disease Dental crowding

Intervention groups

Case group: sodium fluoride mouthwash is used on the gums around the ssc Control group: Chlorhexidine mouthwash is used on the gums around the ssc

Main outcome variables

Determination of plaque index and gingival index in the group treated with chlorhexidine mouthwash
Determining plaque index and gingival index in the group treated with sodium fluoride mouthwash

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230122057176N1**

Registration date: **2023-06-21, 1402/03/31**

Registration timing: **prospective**

Last update: **2023-06-21, 1402/03/31**

Update count: **0**

Registration date

2023-06-21, 1402/03/31

Registrant information

Name

Mobin Nikoonahad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 84 3224 6899

Email address

nikoonahad.mobin@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-26, 1402/04/05

Expected recruitment end date

2023-08-11, 1402/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparson of the effect of Chlorhexidine mouthwash and sodium fluoride mouthwash on gingival healing around stainless steel crown in primary teeth

Public title

comparison of the effect of Chlorhexidine mouthwash and sodium fluoride mouthwash on gingival healing around stainless steel crown in primary teeth

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

6 to 12 year old child Having at least 1 posterior primary tooth that requires a stainless steel crown

Exclusion criteria:

Child with systemic disease Child with dental crowding

Age

From **6 years** old to **12 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Patient : the patient does not know the type of mouthwash. After obtaining the consent form from the patient, the relevant mouthwash is poured into special containers that have been prepared in advance and the type of mouthwash inside is not known and is delivered to the patient for use. Outcome assessor :the type of mouthwash is not mentioned in the evaluation form and only the patient's code is written. In a separate list, in front of each patient's name, the relevant code and the name of the mouthwash are written so that the analyzer can use that list to perform the analysis. In this way, the evaluator does not know the name of the patient and the type of mouthwash.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ilam University of Medical Sciences

Street address

6939177143, Pegohesh Boulevard, Banganjab, Ilam

City

Ilam

Province

Ilam

Postal code

6939177143

Approval date

2023-06-18, 1402/03/28

Ethics committee reference number

IR.MEDILAM.REC.1402.058

Health conditions studied

1

Description of health condition studied

Gingivitis

ICD-10 code

K05.1

ICD-10 code description

Chronic gingivitis

Primary outcomes

1

Description

Plaque index

Timepoint

At the beginning of the study and 7 days after the intervention

Method of measurement

Turesky modification of the Quigley-Hein method

2

Description

Gingival index

Timepoint

At the beginning of the study and 7 days after the intervention

Method of measurement

Löe & silness method

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: vi one mouthwash made by Rogin company is used for one week and twice a day in children 6 to 12 years old.

Category

Treatment - Drugs

2

Description

Control group: chlorhexidine mouthwash made by Rogin company is used for one week and twice a day in children 6 to 12 years old.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ilam University of Medical Sciences

Full name of responsible person

Mobin Nikoonahad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ilam University of Medical Sciences

Full name of responsible person

Abas Maleki

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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

Ilam 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

Ilam University of Medical Sciences

Full name of responsible person

Mobin Nikoonahad

Position

student

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Full can be published

When the data will become available and for how long

6 months after the results are published

To whom data/document is available

Only people working in academic institutions

Under which criteria data/document could be used

No analysis is allowed

From where data/document is obtainable

Mobin Nikoonahad nikoonahad.mobin@gmail.com

What processes are involved for a request to access data/document

It is reviewed by Mobin Nikonhad

Comments