

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Comparison of the effects of chlorhexidine, Persica and Protact mouthwash on gingival healing after crown lengthening surgery: a double-blinded randomized clinical trial

Protocol summary

Study aim

Determining the effect of chlorhexidine, Persica and Protact mouthwashes on gingival healing after crown lengthening surgery

Design

A randomized clinical trial in the form of a randomized block with a control group, with parallel groups, double-blind on 33 patients. Choosing the type of group for each person through random allocation software 2

Settings and conduct

The study will be conducted on patients referred to Sari Dental Faculty who are candidates for tooth crown lengthening surgery. The study is double-blind and to blind the patients and the surgeon (researcher), the mouthwashes will be placed in the same dark bottles with different labels. Patients will use mouthwash for 2 weeks from the night of surgery, and then the variables will be checked and recorded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients between 18 and 60 years old with indication of crown lengthening surgery
Exclusion criteria: systemic disease, smokers, pregnant and breastfeeding women, being allergic to mouthwashes, using antibiotics in the last 3 months for 10 consecutive days, using drugs that interfere with gum healing and corticosteroids,

Intervention groups

Patients will be divided into three groups. Each group will be given one of chlorhexidine 0.2%, Persica and Protact mouthwashes. the patients will be asked to use mouthwashes for two weeks from the night of surgery according to the manufacturer's recommendations, and avoid washing their mouths, eating and drinking for half an hour after using the mouthwash. After surgery, all patients will be prescribed ibuprofen 400mg.

Main outcome variables

mouthwash taste through questionnaire and gingival

index; Plaque index; Stain index and tongue color change are checked and recorded by the periodontist

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170502033770N2**

Registration date: **2023-06-11, 1402/03/21**

Registration timing: **registered_while_recruiting**

Last update: **2023-06-11, 1402/03/21**

Update count: **0**

Registration date

2023-06-11, 1402/03/21

Registrant information

Name

Hodis Ehsani

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3325 4135

Email address

hehsani@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-10, 1402/03/20

Expected recruitment end date

2023-07-06, 1402/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of chlorhexidine, Persica and Protact mouthwash on gingival healing after crown lengthening surgery: a double-blinded randomized clinical trial

Public title

The effect of Persica and Protact herbal mouthwashes on the wound of gum surgery

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients should be between 18 and 60. Patients with indications for clinical crown lengthening surgery on at least one tooth. Patients agree to participate in the study.

Exclusion criteria:

They have used antibiotics for 10 consecutive days in the past 3 months. They are allergic to mouthwash. Patients have diabetes or any other systemic disease. Patients take medications that interfere with gum healing, such as contraceptives. They use corticosteroids. They are pregnant or breastfeeding. They use cigarettes. They have pathological lesions in the oral mucosa. They have removable dental prostheses or orthodontics. They have periodontitis in the surgical area. The teeth are discolored due to systemic factors or drugs.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **33**

Randomization (investigator's opinion)

Randomized

Randomization description

Random block method will be used to assign samples to groups (type of mouthwash). First, the samples will be matched in terms of age, gender, periodontium condition and oral hygiene and people with similar status will be placed in a block. According to the total number of required samples (33 samples) and the number of mouthwashes, finally 11 blocks with matched samples will be considered as 3 samples in each block (number of mouthwashes). Selection of blocks and type of mouthwash for each sample will be done through random allocation software 2 and the samples will be placed in one of the groups by this software.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study is double-blind. In order to blind patients, therapists and researchers, mouthwashes are placed in dark-colored bottles with the same appearance with different labels and are prescribed along with painkillers. According to the recommendations of the manufacturers, the mouthwash instructions leaflet is given to the patients in identical envelopes with different labels according to the mouthwash label, and the patients are asked to use the relevant mouthwash according to the leaflet.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Mazandaran University of Medical Sciences

Street address

Khazar Blvd, Sari Faculty of Dentistry (Tooba dental clinic)

City

Sari

Province

Mazandaran

Postal code

4816895475

Approval date

2023-01-24, 1401/11/04

Ethics committee reference number

IR.MAZUMS.REC.1401.491

Health conditions studied**1****Description of health condition studied**

Clinical dental crown lengthening surgery

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

gingival index (GI)

Timepoint

Measurement of gingival index on the day of surgery and

14 days after surgery
Method of measurement
by periodontal probe

2

Description

plaque index (PI)

Timepoint

Measurement of plaque index on the day of surgery and
14 days after surgery

Method of measurement

by dental explorer

Secondary outcomes

1

Description

Stain index (SI)

Timepoint

14 days after surgery

Method of measurement

by periodontal probe

2

Description

Changing the color of the tongue

Timepoint

14 days after surgery

Method of measurement

observation

3

Description

taste of the mouthwash

Timepoint

14 days after surgery

Method of measurement

questionnaire

Intervention groups

1

Description

Control group: This group will be given Chlorhexidine 0.2% mouthwash (Iran Najo Company) and they will be asked to use 10 ml of mouthwash and swish it in their mouth for 30 seconds twice a day in the morning and at night after brushing teeth according to the manufacturer's recommendation for two weeks from the night of surgery. Patients will be asked to avoid washing their mouth, eating and drinking for half an hour after using the mouthwash. Also, after surgery, all patients will be prescribed ibuprofen 400mg

Category

Treatment - Drugs

2

Description

Intervention group: This group (the first intervention group) will be given Persica mouthwash (Porsina company) and they will be asked to dilute 15 drops of mouthwash with 15 ml of water and swish it in their mouth for 20 seconds 4 times a day according to the manufacturer's recommendation for two weeks from the night of surgery. Patients will be asked to avoid washing their mouth, eating and drinking for half an hour after using the mouthwash. Also, after surgery, all patients will be prescribed ibuprofen 400mg.

Category

Treatment - Drugs

3

Description

Intervention group: This group (the second intervention group) will be given Protact mouthwash (Zolangrespina company) and they will be asked to use 5 ml of mouthwash and swish it in their mouth for 1 minute 3 times a day (after breakfast, lunch and at night after brushing teeth) according to the manufacturer's recommendation for two weeks from the night of surgery. Patients will be asked to avoid washing their mouth, eating and drinking for half an hour after using the mouthwash. Also, after surgery, all patients will be prescribed ibuprofen 400mg.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sari Faculty of Dentistry

Full name of responsible person

Hadis Ehsani

Street address

Khazar Blvd, Sari Faculty of Dentistry

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Sari

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4816895475

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Email

hehsani@mazums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

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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

Mazandaran 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**

Mazandaran University of Medical Sciences

Full name of responsible person

حديث احسانی

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Phone

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Email

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Person responsible for scientific**inquiries****Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Hadis Ehsani

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Hadis Ehsani

Position

Assistant Professor

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

Title and more details about the data/document

After the completion of the project, the results will be delivered in the form of a final report and in electronic form (on a CD) to the Vice-Chancellor of Research and Faculty of Dentistry of Mazandaran University of Medical Sciences.

When the data will become available and for how long

The decision regarding access to the data will be the responsibility of the vice president of research and the Faculty of Dentistry of Mazandaran University of Medical

Sciences, as well as the supervisor.

To whom data/document is available

Vice President of Research, Faculty of Dentistry, Mazandaran University of Medical Sciences and also a supervisor

Under which criteria data/document could be used

The request should be sent to the responsible person after consultation with the research team, the data will be provided to the requesting person, and it is necessary to give reference to the data owners in the articles or wherever the data is to be used, and the use of the results only It is allowed by citing its source.

From where data/document is obtainable

Vice President of Research, Faculty of Dentistry, Mazandaran University of Medical Sciences and also a supervisor

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

A written request to the vice president of research or the Faculty of Dentistry of Mazandaran University of Medical Sciences and also obtaining the consent of the supervisor.

Comments