Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of effect of 15% benzydamine mouthwash on pain perception during palatal local anesthesia injection in patients candidated for periodontal surgery.a cross-clinical trial

Protocol summary

Study aim
Evaluation of effect of 15% benzydamine mouthwash on pain perception during palatal local anesthesia injection in patients candidated for periodontal surgery

Design
A clinical trial with a control group, cross-over groups, double-blind, randomized with phase 3, on 86 patients, was used to randomize the Rand function of Excel software.

Settings and conduct
: Guilan Faculty of Dentistry Clinic. How to notify people to enter the plan: from among the people who refer to Guilan Dental School.

Participants/Inclusion and exclusion criteria
People 20-60 years old / with systemic health (without cardiovascular diseases, high blood pressure, diabetes, thyroid diseases, liver, etc.) who need maxillary posterior sextant crown lengthening surgery/gum graft/flap surgery in Posterior sextants have high jaws. Exclusion criteria: 1. Presence of diabetes, cardiovascular disease and hypertension 2. Cigarettes 3. Taking NSAIDS drugs during the last 6 months 4. Pregnancy 5. Taking painkillers within 24 hours before surgery

Intervention groups
Intervention group: the use of 15cc of 0.15% benzydamine hydrochloride mouthwash for each patient is gargled for one minute. Control group: the use of 15cc of washing serum for each patient is done by mouth gargling for one minute.

Main outcome variables
The amount of pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221012056154N1**
Registration date: **2022-12-03, 1401/09/12**
Registration timing: **registered_while_recruiting**

Last update: **2022-12-03, 1401/09/12**
Update count: **0**

Registration date
2022-12-03, 1401/09/12

Registrant information

Name
Sheida Dadashi navi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 13 4426 1771

Email address
sheida.dadashi71@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-10-23, 1401/08/01

Expected recruitment end date
2023-03-21, 1402/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of effect of 15% benzydamine mouthwash on pain perception during palatal local anesthesia injection in patients candidated for periodontal surgery.a cross-

clinical trial

Public title

"The effect of 0.15% benzydamine mouthwash on pain perception "during local palatal injection in periodontal surgery candidates

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

People 20-60 years old / with systemic health (without cardiovascular diseases, high blood pressure, diabetes, thyroid diseases, liver, etc.) People who need maxillary posterior sextant crown lengthening surgery. People who need gum grafts. People who need flap surgery in the posterior sextant of the maxilla

Exclusion criteria:

1. Presence of diabetes, cardiovascular disease and hypertension Smoking Taking NSAIDS drugs in the last 6 months Pregnancy Taking painkillers within 24 hours before surgery

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **86**

More than 1 sample in each individual

Number of samples in each individual: **2**

1. Presence of diabetes, cardiovascular disease and hypertension 2. Cigarettes 3. Taking NSAIDS drugs in the last 6 months 4. Pregnancy 5. Taking painkillers within 24 hours before surgery

Randomization (investigator's opinion)

Randomized

Randomization description

Based on the gradual sampling method of visiting the clinic, the patients were divided into two groups using 0.15% benzyd amine hydrochloride mouthwash (43 people) and using washing serum as a placebo group based on four random blocks. 43 people) are randomly assigned. The method used to generate the random allocation sequence by mentioning the name of the software or the site used: the random allocation sequence based on www.sealede envelope.com and the Random Block software will be used online. Then, in order to hide, the sequence list in the center The dental school research will be placed in a sealed envelope. After the permission to run this clinical trial, the type of interventions will be determined from inside the envelope based on the list in the daily visits of the patients.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients and operators are aware of the type of general grouping (which is divided into two categories of using benzydamine mouthwash and washing serum), but they do not know the order of entry into the grouping.. Before performing the work, two containers of the same color, whose contents cannot be distinguished from each other, are prepared by a person other than the operator and the patients, then before the operation, two containers are prepared by a person other than the operator and the patients, then Washing serum (Shahid Ghazi Company-Iran) is placed in one container and 0.15% benzyd amine hydrochloride mouthwash (Elixir Borujard Company-Iran) is placed in another container.First, group A patients are given 15cc of 0.15% benzyd amine hydrochloride mouthwash, and group B patients are given 15cc of serum to gargle for about a minute. After that, by the operator, for all the subjects, an infiltration injection with lidocaine 2% (1:100,000 epinephrine) (Exir Borujerd Company, Iran) was performed in the right posterior sextant of the upper jaw with an injection syringe and a 27 gauge dental needle with a length of 30 mm. can be The operator then scored the VAS (Vas is scored on a 100 mm horizontal line with the left endpoint marked "no pain" and the right endpoint "pain as bad as it can be.") for each patient. It registers immediately after the injection. All necessary surgical procedures are performed for each patient.In the next session, two containers whose contents cannot be distinguished from each other are prepared by someone other than the operator and the patients, in one container washing serum (Shahid Ghazi Pharmaceutical Company - Iran) and in the other container 0.15 benzyd amine hydrochloride mouthwash. % (Broujerd Elixir Company-Iran) is placed. Half of the patients who were given 15cc of 0.15% benzyd amine hydrochloride mouthwash last week are given 15cc of serum to gargle for about a minute. And vice versa, 15cc of benzydamine hydrochloride mouthwash is given to the patients who were washed with serum last week to gargle.After that, by the operator, this time for all the subjects in the left posterior sextant of the upper jaw, an infiltration injection with lidocaine 2% (1:100000 epinephrine) (Exir Borujerd Company-Iran) with an injection syringe and a 27-gauge dental needle head. 30mm is done. Then the operator records the VAS again for each patient immediately after the injection. Again, all surgical procedures are performed according to the previous procedure.

Placebo

Used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
کمیته اخلاق دانشگاه علوم پزشکی گیلان
Street address
Gilan, Rasht, Namjo St., Shahid Siyadati St., in front of 17 Shahrivar Hospital
City
rasht
Province
Guilan
Postal code
4144666949
Approval date
2022-06-29, 1401/04/08
Ethics committee reference number
ir.gums.rec.1401.154

Health conditions studied

1

Description of health condition studied
Chronic periodontitis
ICD-10 code
K05.3
ICD-10 code description
Chronic periodontitis

Primary outcomes

1

Description
intensity of pain
Timepoint
Immediately after the start of the intervention
Method of measurement
visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: For each patient, 15cc of benzydamine hydrochloride 0.15% mouthwash (Shahid Ghazi Company, Iran) is administered for 1 minute.
Category
Treatment - Drugs

2

Description
Control group: For each patient, 15 cc of washing serum (Shahid Qazi Company - Iran) is gargled for 1 minute.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Guilan Faculty of Dentistry Clinic
Full name of responsible person
ashkan salari
Street address
Rasht-Saravan Road to Foman-Gilan Dental Clinic
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sheida.dadashi@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Dr.mohammad reza naghipour
Street address
Gilan, Rasht, Namjo St., Shahid Siyadati St., in front of 17 Shahrivar Hospital
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4144666949
Phone
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Email
research@gums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Rasht 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
Rasht University of Medical Sciences
Full name of responsible person
ashkan salari
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

Contact
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Position
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Latest degree
Specialist
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Rasht-Saravan Road to Foman-Gilan Dental Clinic
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Drashkan_salary@yahoo.com

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
Yes - There is 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
Age, gender, pain level of the study group All data can potentially be released after identifying individuals
When the data will become available and for how long
Access starts 6 months after the results are published
To whom data/document is available
For researchers working in academic and scientific institutions and people working in industry.
Under which criteria data/document could be used
It can be used for research work or comparison with the intended study. It is possible to access the data by referring to the Research Science Center of Gilan Faculty of Dentistry and the person in charge, Mrs. Alavi.
From where data/document is obtainable
It is possible to access the data by referring to the Research Science Center of Gilan Faculty of Dentistry and the person in charge, Mrs.sana Alavi. Responsible persons: Shida Dadashi Navi 09387181876 Mrs. Alavi: 09119431009
What processes are involved for a request to access

data/document

First, refer to the Science Research Center of the Faculty of Dentistry. Then they will be referred to the responsible person, Mrs. Shida Dadashi Navi, after the approval of the responsible person, it is possible to access the data.

Comments