Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Investigating the effect of combined mouthwash of chlorhexidine, benzydamine, nanosilver and antibiotics in improving the amount of pain and maximum opening of the mouth of perichronitis patients: a randomized controlled clinical trial

Protocol summary

Study aim
Determining the effect of combined mouthwash of chlorhexidine, benzydamine, nanosilver and antibiotics amoxicillin and metronidazole in improving the amount of pain and MMO (maximum opening of the mouth) of perichronitis patients.

Design
randomised controlled trial, parallel group, double blind, phase 3 on 58 patients

Settings and conduct
The location of the Gorgan Dental School

Participants/Inclusion and exclusion criteria
Eligibility criteria: acute perichronitis; the need to be available during the research process; Having informed consent Criteria for not entering the study: presence of chronic systemic disease; receiving systemic or local antibiotic therapy in the last 3 months; chronic perichronitis; symptoms of severe perichronitis; periodontal disease in the area of perichronitis; smoking; alcohol consumption; pregnancy and breastfeeding; allergy

Intervention groups
The control group was given mouthwash containing 0.12% chlorhexidine, and the case group was given a combined mouthwash containing chlorhexidine, benzydamine, nano silver and antibiotics amoxicillin and metronidazole.

Main outcome variables
pain; maximum opening of the mouth

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230104057046N1**
Registration date: **2023-03-12, 1401/12/21**
Registration timing: **registered_while_recruiting**

Last update: **2023-03-12, 1401/12/21**
Update count: **0**

Registration date
2023-03-12, 1401/12/21

Registrant information

Name
Nazanin Mortazavi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 17 3254 5671

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-02-20, 1401/12/01

Expected recruitment end date
2023-06-22, 1402/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of combined mouthwash of chlorhexidine, benzydamine, nanosilver and antibiotics in improving the amount of pain and maximum opening of

the mouth of perichronitis patients: a randomized controlled clinical trial

Public title
Investigating the effect of combined mouthwash of chlorhexidine, benzydamine, nanosilver and antibiotics in perichronitis patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Acute perichronitis The need to be available during the research process Having informed consent

Exclusion criteria:
presence of chronic systemic disease (diabetes, kidney disease) receiving systemic or local antibiotic therapy in the last 3 months chronic perichronitis symptoms of severe perichronitis such as fever (<38.3°C) and facial swelling Periodontal disease in the area of perichronitis Smoking Alcohol consumption Pregnancy and breastfeeding Allergy to amoxicillin or non-steroidal anti-inflammatory drugs

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **58**
More than 1 sample in each individual
Number of samples in each individual: **29**
Based on random allocation, patients will be placed in one of the two groups of case or control, and they have no idea of the type of mouthwash received. The control group was given mouthwash containing 0.12% chlorhexidine, and the case group was given a combined mouthwash containing chlorhexidine, benzydamine, nanosilver and antibiotics amoxicillin and metronidazole.

Randomization (investigator's opinion)
Randomized

Randomization description
In the Excel software, we enter 29 items A and 29 items B in one column. In the opposite column, we generate random numbers using the rand() command, and sorting from small to large can be done based on the second column. One of the implementation plans that evaluates the messages does not give, it pastes the web letters that only it knows about which one it is related to and which of the drugs it knows on the drug drug and the drug listed in Excel is in order . It will be allocated to referring patients.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants and experimenters were blinded (double-blind). The bottles containing medicine are the same for both the control and intervention groups, and the intervention and control groups are divided into two groups, A and B, but the experimenter has no knowledge of these two groups, and the participants of the experiment have no knowledge of the type and group of the case. They don't have a test. The data analyst also has no knowledge of the tested group.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Golestan University of Medical Sciences

Street address
Agh Qola city, Ataabad village, Farhang street, Farhang first alley

City
Gorgan

Province
Golestan

Postal code
4938136953

Approval date
2022-04-20, 1401/01/31

Ethics committee reference number
IR.GOUMS.REC.1401.016

Health conditions studied

1

Description of health condition studied
pericoronitis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Pain

Timepoint
Examining the amount of pain before using mouthwash and on days 1, 2, 3, 4, 5, 6 and 7 after using combined mouthwash compared to chlorhexidine mouthwash in perichronitis patients.

Method of measurement
The amount of pain will be measured according to the standard VAS scale on a 100 mm chart.

2

Description
"Maximum mouth opening of pericroniitis patients"
Timepoint
Investigating the amount of maximum mouth opening before using mouthwash and on days 1, 2, 3, 4, 5, 6 and 7 after using combined mouthwash compared to chlorhexidine mouthwash in perichronitis patients
Method of measurement
The maximum amount of mouth opening by a graduated ruler

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention group is provided with a combined mouthwash containing chlorhexidine, benzydamine, nanosilver and antibiotics amoxicillin and metronidazole. Each study subject receives a 280 ml bottle containing mouthwash. Use 20 ml of mouthwash for 7 days. The mouthwashes are made by a pharmacist who is a consultant in the project.
Category
Treatment - Drugs

2

Description
Control group: The control group will be given mouthwash containing 0.12% chlorhexidine. Each study subject will receive a 280 ml bottle containing mouthwash, each patient will be taught to use 20 ml each time for 7 days Use mouthwash daily.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Gorgan Faculty of Dentistry
Full name of responsible person
Neman Arekhi
Street address
Agh Qola city, Ataabad village, Farhang street, Farhang first alley
City
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Postal code
4938136953
Phone
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Email
nemanarekhi@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
Narges Begum Mirbehbani
Street address
Golestan Province, Gorgan, Shahrek Shahrek, Shahrear 5, Gorgan Faculty of Dentistry, Dental Research Center
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4913983635
Phone
+98 17 3262 8052
Email
nemanarekhi@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Gorgan 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
Gorgan University of Medical Sciences
Full name of responsible person
Neman Arekhi
Position
Dentistry student
Latest degree
A Level or less
Other areas of specialty/work
Dentistry
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Person responsible for scientific inquiries

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Neman Arekhi
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Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Position
Dentistry student
Latest degree
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Other areas of specialty/work
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Golestan
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Phone
+98 17 3450 2115
Fax
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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
Yes - There is 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
Potential data can be shared after de-identifying individuals
When the data will become available and for how long
The access period starts 6 months after the results are published
To whom data/document is available
Researchers working in academic and scientific institutions in the country can access the data and other documents of this study by writing a request from (Gorgan Dental School Research Center).
Under which criteria data/document could be used
The documents will be available to the applicants after obtaining permission from the project managers and the research director of Golestan University of Medical Sciences and with a written request from (Gorgan Dental School Research Center). Obviously, the administrative procedures take time and we try to complete the application within one month from the date of application.
From where data/document is obtainable
Gorgan, Shahrek Shahryar, Shahryar 5, Gorgan Faculty of Dentistry, Dental Research Center, Mrs. Shabani, Research Center Expert. Postal code 4913983635 phone number 017 3262 2885 email: s.shabani8791@gmail.com
What processes are involved for a request to access data/document
Researchers working in academic and scientific institutions in the country can access the data and other documents of this study by writing a request from (Gorgan Dental School Research Center). The documents will be available to the applicants after obtaining permission from the project managers and the research director of Golestan University of Medical Sciences. Obviously, the administrative procedures take time and we try to complete the application within one month

from the date of application.

Comments