Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation the effect of distilled water, chlorhexidine mouthwash and ethanolic extract of Peganum Harmala plant on the count of Streptococcus mutans settled on removable orthodontic appliances

Protocol summary

Study aim

Evaluation the effect of distilled water, chlorhexidine mouthwash and ethanolic extract of Peganum Harmala plant on the count of Streptococcus mutans settled on removable orthodontic appliances

Design

A clinical trial with control group ,with a single design ,without blinding ,non-randomized ,phase 1-2 , on 30 patients

Settings and conduct

The number of 30 patients referred to the orthodontic department of the clinic of the dental school of Ilam province is selected. Due to the difference in the microbial flora of the people's mouths, the comparison between the amount of flora obtained from each person's test and his own. During 10-day cycles, 3 containers are given to the patients to place the orthodontic plaques inside when they are removed from the mouth. At the end, the flora obtained from each of these three containers will be compared with that person's own container. We will compare container 1, 2 and 3 for each person) and then make a general conclusion. - Method of work in order: entry of patients into the study, obtaining informed consent, molding and preparation of retainer, sampling and determination of MIC and MBC of herbal extract, delivery of orthodontic plate and dishes to patients in 10-day periods respectively - analysis

Participants/Inclusion and exclusion criteria

entering the study:prescription of orthodontic retainer by a specialist - age 20-60 years not entering the study: active periodontal disease - History of using chlorhexidine mouthwash during the last two weeks

Intervention groups

Intervention1(Chlorhexidine mouthwash)- Intervention2(Ethanol extract of Paganum harmala plant)

Main outcome variables

the count of Streptococcus mutans settled on removable orthodontic appliances .

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221030056345N1**
Registration date: **2023-07-16, 1402/04/25**
Registration timing: **registered_while_recruiting**

Last update: **2023-07-16, 1402/04/25**
Update count: **0**

Registration date

2023-07-16, 1402/04/25

Registrant information

Name

Fatemeh Jafarzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 84 3385 3746

Email address

doctorfj1999@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-06, 1402/04/15

Expected recruitment end date

2023-08-06, 1402/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of distilled water, chlorhexidine mouthwash and ethanolic extract of Peganum Harmala plant on the count of Streptococcus mutans settled on removable orthodontic appliances

Public title

Evaluation the effect of distilled water, chlorhexidine mouthwash and ethanolic extract of Peganum Harmala plant on the count of Streptococcus mutans settled on removable orthodontic appliances

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Consent of participants to participate in the study Retainer prescription by an orthodontic specialist Age 20-60 years

Exclusion criteria:

Active periodontal disease History of using chlorhexidine mouthwash during the last two weeks

Age

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

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research ethics committees of ilam university of medical sciences

Street address

Pardis of Ilam University of Medical Sciences ,Paghoohesh Blvd,Banganjab,Ilam

City

Ilam

Province

Ilam

Postal code

6939177143

Approval date

2023-06-17, 1402/03/27

Ethics committee reference number

IR.MEDILAM.REC.1402.038

Health conditions studied

1

Description of health condition studied

the count of Streptococcus mutans settled on removable orthodontic appliances

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

count of Streptococcus mutans settled on removable orthodontic appliances

Timepoint

10 days after the intervention

Method of measurement

Through microbial culture and colony counting

Secondary outcomes

empty

Intervention groups

1

Description

Control: Distilled water-ph=6.5-7.5-TDS=0.00ppm-CL=0.00-once for 30 participants in a 10-day period-after removing the movable orthodontic plate from the mouth, the participant will immerse it in a container containing distilled water. and to put it back in the mouth, he will use tweezers to remove the mobile plaque from distilled water. After 10 days, the solution will be cultured - Sina Noor Company

Category

N/A

2

Description

First Intervention: The first intervention group: Chlorhexidine 0.2% - mouthwash - every 100 ml containing: chlorhexidine gluconate 0.2 g + 10% ethanol - Najo company - the participant for 10 days after removing the removable orthodontic plate from the mouth, put it in a container containing Chlorhexidine

mouthwash will be immersed and forceps will be used to remove the mobile plaque from the mouthwash to put it back in the mouth. After 10 days, the solution will be cultured.

Category

Treatment - Drugs

3

Description

Second Intervention: Ethanol extract of pecan plant-combination: 600 grams of pecan is prepared for the preparation of herbal mouthwash. After washing and drying, the fruit and seeds of the plant will be separated and ground with a grinder. The resulting powder is poured into a container and Its surface is completely covered with 96% ethanol and it remains in this state for 48 hours. Then the resulting mixture is placed in the oven. After 72 hours, when the solution remains in the oven, the solution is removed from the machine and passed through filter paper. Then the resulting solution is placed in the rotary device little by little and several times. And in this way, the alcohol is separated from the solution and a liquid is obtained, which after drying will be the same pecan plant extract that is used to prepare Different concentrations will be dissolved in normal saline serum.-The concentration used in the study will be lower than MTT (the highest value obtained from MIC determination) - the participant will immerse the movable orthodontic plate in a container containing pecan plant mouthwash for 10 days after removing it from the mouth. Placing it back in the mouth will use forceps to remove the moving plaque from the solution. After 10 days, the solution will be cultured.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Facuity of dentistry, ilam university of medical scienes,Ilam,Iran

Full name of responsible person

Parisa Kazemi

Street address

Faculty of Dentistry (old Parsian building)-pardis2-the end of the paghoohesh Blvd-Bangjnab-Ilam

City

ilam

Province

Ilam

Postal code

6939177143

Phone

+98 84 3223 8499

Fax

Email

kazemip222@gmail.com

Web page address

https://dentistry.medilam.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ilam University of Medical Sciences

Full name of responsible person

Sobhan ghafurian

Street address

Paghoohesh Blvd

City

Ilam

Province

Ilam

Postal code

6939177143

Phone

+98 84 3222 7134

Email

info@medilam.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

ilam university of medical sciences

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Ilam University of Medical Sciences

Full name of responsible person

Fatemeh Jafarzadeh

Position

Dentistry student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

Street address

Amirkabir

City

Ilam

Province

Ilam

Postal code

6931836116
Phone
+98 84 3385 3746
Fax
Email
doctorfj99@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Ilam University of Medical Sciences
Full name of responsible person
Fatemeh Jafarzadeh
Position
Dentistry student
Latest degree
A Level or less
Other areas of specialty/work
Dentistry
Street address
Amirkabir
City
Ilam
Province
Ilam
Postal code
6931836116
Phone
+98 84 3385 3746
Fax
Email
doctorfj99@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Ilam University of Medical Sciences
Full name of responsible person
Fatemeh Jafarzadeh
Position
dentistry student
Latest degree
A Level or less
Other areas of specialty/work
Dentistry
Street address
Amirkabir
City
Ilam
Province
Ilam
Postal code
۶۹۳۱۸۳۱۱۶
Phone
+98 84 3385 3746
Email
doctorfj1999@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is 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
Without mentioning the name of the participants, the amount of MIC and MBC of the plant extract and cfu obtained from the three materials used will be shared.
When the data will become available and for how long
The access period will start 1 year after the results are published
To whom data/document is available
The data will be accessible to researchers working in academic and scientific institutions and students interested in research
Under which criteria data/document could be used
Data access is allowed if researchers use them to increase awareness and interest in conducting further studies
From where data/document is obtainable
Email address: doctorfj1999@yahoo.com
What processes are involved for a request to access data/document
Applicants should include researchers working in academic and scientific institutions or students who, after sending the documents to the email address doctorfj1999@yahoo.com and mentioning the purpose of the data study, the result will be sent to them via email within 2-3 months at most. becomes
Comments