

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of antimicrobial properties of coconut oil, moringa oleifera and chlorhexidine on oral bacterial populations

#### Protocol summary

##### Study aim

The aim of this investigation is to determine the efficacy of coconut oil and moringa oleifera as antimicrobials in the oral cavity in comparison to chlorhexidine.

##### Design

Randomized, parallel group, unblinded clinical trial.

##### Settings and conduct

The participants will be recruited at the dental clinics at Riphah International University over a period of 4 weeks. Each participant will be required to sign a consent form before proceeding with the trial.

##### Participants/Inclusion and exclusion criteria

Individuals who maintain good oral health will be enrolled in the study. Those with periodontal disease, systemic illnesses or medications that affect periodontal health will be excluded. People with recent history of oral prophylaxis or antibiotic use will also be excluded.

##### Intervention groups

The participants will be divided into 3 different groups, coconut oil (C), moringa oleifera (M) and chlorhexidine (Control). Each participant will be given a unique number. All 3 groups; with 30 participants each, will be sampled for plaque and gingival crevicular fluid from the lingual surface of lower incisors. The collected sample will be placed will be transported to the laboratory for detailed microbiologic analysis. Each group will be given a specially formulated mouthwash according to their allocation. These participants will be instructed to rinse will 15 mL mouthwash twice daily for 14 days. Reminder text messages will be sent twice daily to ensure compliance. Each participant will be sampled again following completion of 2 weeks. The pre-mouthwash microbial results will be compared with the post-mouthwash samples.

##### Main outcome variables

The difference of the pre-mouthwash and post-mouthwash oral microbial species will be compared.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210212050332N1**

Registration date: **2021-02-16, 1399/11/28**

Registration timing: **prospective**

Last update: **2021-02-16, 1399/11/28**

Update count: **0**

##### Registration date

2021-02-16, 1399/11/28

##### Registrant information

##### Name

Amber Kiyani

##### Name of organization / entity

Riphah International University

##### Country

Pakistan

##### Phone

+92 51 2891835

##### Email address

akiyani@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-06-22, 1400/04/01

##### Expected recruitment end date

2021-07-23, 1400/05/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Comparison of antimicrobial properties of coconut oil, moringa oleifera and chlorhexidine on oral bacterial populations

## Public title

Effect on coconut oil, moringaoleifera and chlorhexidine on oral health.

## Purpose

Prevention

## Inclusion/Exclusion criteria

### Inclusion criteria:

Good oral hygiene. Good brushing habits.

### Exclusion criteria:

Periodontal disease. Systemic disease affecting periodontal health. Recent history of oral prophylaxis. Recent history of antibiotic use.

## Age

From **18 years** old to **40 years** old

## Gender

Both

## Phase

1

## Groups that have been masked

*No information*

## Sample size

Target sample size: **90**

## Randomization (investigator's opinion)

Not randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

1

### Ethics committee

#### Name of ethics committee

Institutional Review Committee, Riphah International University

#### Street address

Riphah International University, Islamic International Dental College, 7th Avenue, G-7/4

#### City

Islamabad

#### Postal code

44000

## Approval date

2017-10-06, 1396/07/14

## Ethics committee reference number

IIDC/IRC/2017/10/006

## Health conditions studied

1

### Description of health condition studied

Caries

### ICD-10 code

K02.9

### ICD-10 code description

Dental caries, unspecified

2

### Description of health condition studied

Periodontitis

### ICD-10 code

K05.6

### ICD-10 code description

Periodontal disease, unspecified

## Primary outcomes

1

### Description

Oral microbial populations

### Timepoint

2 weeks

### Method of measurement

Culture, PCR, biochemical methods

## Secondary outcomes

empty

## Intervention groups

1

### Description

Intervention group: (Coconut oil). 30 individuals in this group will be sampled from the sub gingival area of the lingual surfaces of lower central incisors. The plaque and gingival crevicular fluid collected will be sent for detailed microbiologic analysis (PCR, biochemical testing, bacterial culture). All individuals will be given an emulsion of non-hydrogenated coconut oil as a mouthwash. The participant will be requested to rinse with 15 mL emulsion twice daily. On day 14, the participant will be undergo microbiologic analysis again from the same site.

### Category

Treatment - Drugs

2

### Description

Intervention group: (Moringa Oleifera). 30 individuals in this group will be sampled from the sub gingival area of the lingual surfaces of lower central incisors. The plaque and gingival crevicular fluid collected will be sent for detailed microbiologic analysis (PCR, biochemical testing,

bacterial culture). All individuals will be given a mouthwash made with moringa oleifera extract. The participant will be requested to rinse with 15 mL solution twice daily. On day 14, the participant will be undergo microbiologic analysis again from the same site.

**Category**

Treatment - Drugs

**3****Description**

Control group: (Chlorhexidine gluconate). Chlorhexidine gluconate is a gold standard antibacterial for the oral cavity. This is why it will be used in the control group to compare the efficacy of gold standard against the coconut oil and moringa oleifera mouthwashes. 30 individuals in this group will be sampled from the sub gingival area of the lingual surfaces of lower central incisors. The plaque and gingival crevicular fluid collected will be sent for detailed microbiologic analysis (PCR, biochemical testing, bacterial culture). All individuals will be given a 0.2% chlorhexidine. The participant will be requested to rinse with 15 mL solution twice daily. On day 14, the participant will be undergo microbiologic analysis again from the same site.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Riphah International University

**Full name of responsible person**

Amber Kiyani

**Street address**

7th Avenue, G-7/4

**City**

Islamabad

**Postal code**

44000

**Phone**

+92 51 2891835

**Email**

akiyani@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Riphah International University (RARE)

**Full name of responsible person**

Dr. Rahila Yasmin

**Street address**

Al-Mizan IIMCT Complex, 274 Peshawar Rd,  
Rawalpindi, Punjab

**City**

Islamabad

**Postal code**

44000

**Phone**

+92 51 5125162

**Email**

raheela.yasmin@riphah.edu.pk

**Grant name**

RARE Seed Grant

**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Riphah International University (RARE)

**Proportion provided by this source**

50

**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**

Academic

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

Riphah International University

**Full name of responsible person**

Amber Kiyani

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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

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**Other areas of specialty/work**

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**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**

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**

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**

All collected deidentified IPD will be submitted.

**When the data will become available and for how long**

The data will be made available following completion of the project for a 4 week period.

**To whom data/document is available**

Data sharing will be open to all.

**Under which criteria data/document could be used**

The primary investigator will decide on who to release data to.

**From where data/document is obtainable**

Email requests will be accommodated.

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

An email request needs to be sent to the principal investigator.

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

Riphah International University

**Full name of responsible person**

Amber Kiyani

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Assistant Professor

**Latest degree**

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**Other areas of specialty/work**

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