

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of bistort mouthwash with chlorhexidine mouthwash on periodontal indices and oral health-related quality of life in pregnant women with gingivitis.

Protocol summary

Study aim

Comparison of the effect of bistort mouthwash with chlorhexidine mouthwash on periodontal indices and oral health-related quality of life in pregnant women with gingivitis

Design

A controlled clinical trial with parallel groups , triple blind, randomized ,phase 2 on 84 patients. The random assignment sequence of individuals was performed using random allocation software.

Settings and conduct

Study location: Esmetieh health center, under the supervision of Kashmar health network; study population: pregnant women aged 15 to 45 years, between 15 and 28 weeks of gestation, diagnosed with gingivitis; type of blinding: triple-blind; blinding method: mouthwashes will be coded by a third party in identical, unlabeled bottles. The participants, the researcher, and the data analyst will all be blinded to the type of mouthwash.

Participants/Inclusion and exclusion criteria

Inclusion criteria: non-smoking pregnant women aged 15 to 45 years from 15 to 28 weeks of pregnancy; having gingivitis based on validated periodontal indicators; Presence of microbial plaque measured based on scientific indicators; presence of dental pigmentation due to dental infection. Exclusion criteria: lack of willingness to cooperate; having systemic diseases; Use of anti-inflammatory drugs and antibiotics in the past 3 months; severe nausea and vomiting

Intervention groups

Intervention group (bistort mouthwash): used twice daily for 14 days; 5ml each time, rinsed for 30 seconds.
Control group (chlorhexidine mouthwash): used twice daily for 14 days; 5ml each time, rinsed for 30 seconds.

Main outcome variables

Oral health-related Quality of life score ; Gingivitis Index;

Plaque Index; stain index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241221064118N1**

Registration date: **2025-06-14, 1404/03/24**

Registration timing: **prospective**

Last update: **2025-06-14, 1404/03/24**

Update count: **0**

Registration date

2025-06-14, 1404/03/24

Registrant information

Name

fahimeh ebrahimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5523 2306

Email address

ebrahimisfpp@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-08-23, 1404/06/01

Expected recruitment end date

2025-12-22, 1404/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of bistort mouthwash with chlorhexidine mouthwash on periodontal indices and oral health-related quality of life in pregnant women with gingivitis.

Public title

Effect of bistort mouthwash on pregnancy gingivitis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Pregnant women from 15 to 28 weeks of pregnancy Aged 15 to 45 years Non-smoker Having gingivitis based on validated periodontal indicators Presence of microbial plaque measured based on scientific indicators If the presence of tooth discoloration is due to a dental infection No need for antibiotic prophylaxis

Exclusion criteria:

Use of anti-inflammatory drugs and antibiotics in the past 3 months Nausea and vomiting during pregnancy Having systemic disease Reluctance to cooperate

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

1. The random allocation sequence was generated using random allocation software, with permuted blocks of size four. A total of 21 blocks were created to allocate 84 participants. 2. The randomization sequence was enclosed in sealed opaque envelopes to prevent disclosure of allocation order. 3. After enrollment and obtaining written informed consent, a sealed envelope was opened in numerical order to determine the assigned intervention. this process was conducted by an individual independent of the research team.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Random allocation of participants was performed using random allocation software. which fully ensures allocation concealment. mouthwashes were packaged in identical dark containers. participants ,assessors. investigators. and statisticians were blinded to group allocation (triple-blind study)

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Mashhad University of Medical Sciences

Street address

Daneshgah street

City

Mashhad

Province

Razavi Khorasan

Postal code

1394491388

Approval date

2025-06-01, 1404/03/11

Ethics committee reference number

IR.MUMS.NURSE.REC.1404.027

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

Pregnancy Gingivitis

ICD-10 code

K05

ICD-10 code description

Gingivitis and periodontal diseases

Primary outcomes**1****Description**

Plaque Index

Timepoint

At baseline and two weeks after the intervention

Method of measurement

Clinically assessed by a trained evaluator using the silness & loe plaque index

2**Description**

Gingival index

Timepoint

At baseline and two weeks after the intervention

Method of measurement

clinically assessed by a trained evaluator using the loe & silness Gingival index

3

Description

Stain Index

Timepoint

At baseline and two weeks after the intervention

Method of measurement

Clinically examined and scored using standard visual methods by trained evaluator

4

Description

Oral Health -Related Quality of Life

Timepoint

At baseline and two weeks after the intervention

Method of measurement

Self-reported by participants using the standardized OHIP-14 questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Participants in this group will use bistort mouthwash twice daily for 2 weeks after scaling and receiving routine oral hygiene education. Patients should refrain from eating and drinking for one hour after using the mouthwash.

Category

Prevention

2

Description

Control group: participants in this group will use 0.2% chlorhexidine mouthwash twice daily for 2 weeks after scaling and receiving routine oral hygiene education. Patients should refrain from eating and drinking for one hour after using the mouthwash.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Asmateh health center, Kashmar county, Razavi Khorasan

Full name of responsible person

Fahimeh Ebrahimi

Street address

Asmateh health center, between Imam Khomeini 3 and Imam Khomeini 5, Imam Khomeini street

City

Kashmar

Province

Razavi Khorasan

Postal code

9671616669

Phone

+98 51 5522 7503

Fax

+98 51 5522 7501

Email

ebrahimisfpp@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr.Mohsen Tafaghodi

Street address

Daneshgah street

City

Mashhad

Province

Razavi Khorasan

Postal code

1394491388

Phone

+98 51 3841 1538

Email

tafaghodim@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Fahimeh ebrahimi

Position

midwifery student

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

No.79,Amir Kabir Street, Kashmar,Iran

City

Kashmar

Province

Razavi Khorasan

Postal code

9671986150

Phone

+98 51 5523 0425

Email

ebrahimisfpp@gmail.com

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

Mashhad University of Medical Sciences

Full name of responsible person

Fahimeh Ebrahimi

Position

Midwifery student

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

No.79,Amir Kabir street,Kashmar,Iran

City

Kashmar

Province

Razavi Khorasan

Postal code

9671986150

Phone

+98 51 5523 0425

Email

ebrahimisfpp@gmail.com

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

Mashhad University of Medical Sciences

Full name of responsible person

Fahimeh Ebrahimi

Position

master's student in midwifery

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

No.79,Amir kabir street,Kashmar,Iran

City

kashmar

Province

Razavi Khorasan

Postal code

9671986150

Phone

+98 51 5523 0425

Email

ebrahimisfpp@gmail.com

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

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