Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr.Mohsen Tafaghodi
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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
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Person responsible for updating data

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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
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