Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

comparison of the effects of persica and chamomile herbal mouthwashes in treating pregnancy gingivitis, a double-blind clinical trials

Protocol summary

Study aim
The aim of this study was to investigate the effect of chamomile mouthwashes with persica mouthwash in treating pregnancy gingivitis

Design
This study was a double-blind, controlled trial, 25 patients with gingivitis were assigned in each group.For randomization, the permuted block randomization will be used with quadruple blocks, In order to apply the concealment in the randomization process, unique codes, which is generated by the software, will be used on the drug boxes.

Settings and conduct
All patients referred to Golestan Hospital of Ahvaz, Iran, were assigned randomly in one of the treatment regimens for 4 weeks

Participants/Inclusion and exclusion criteria
Pregnant women in the second trimester of pregnancy (weeks 13 to 28) Having moderate to severe gingivitis (gingival grade> 1) Having at least 20 teeth

Intervention groups
Intervention group 1: Persica mouth wash 3 times a day for 1 months Intervention group 2: Chamomile mouth wash 3 times a day for 1 months

Main outcome variables
Gingival index Plaque index

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20111105008013N4**
Registration date: **2018-10-16, 1397/07/24**
Registration timing: **registered_while_recruiting**

Last update: **2018-10-16, 1397/07/24**
Update count: **0**

Registration date
2018-10-16, 1397/07/24

Registrant information
Name
Amir Siahpoosh
Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 61 3334 2197
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-10-12, 1397/07/20

Expected recruitment end date
2018-11-11, 1397/08/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
comparison of the effects of persica and chamomile herbal mouthwashes in treating pregnancy gingivitis, a double-blind clinical trials

Public title
effect of chamomile herbal mouthwashes in treatment of gingivitis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:

Pregnant women in the second trimester of pregnancy (weeks 13 to 28) Having moderate to severe gingivitis (gingival grade> 1) Having at least 20 teeth Age of 20 to 35 years

Exclusion criteria:

Moderate to severe caries Having systemic diseases, including severe cardiovascular disease, diabetes and hyperthyroidism Receiving periodontal treatment in the last six months Any disorder or chronic / acute infection other than gingivitis History of antibiotic use in recent months Tobacco use history

Age

From **20 years** old to **35 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

For randomization, the permuted block randomization will be used with quadruple blocks. blocks will be produced by using the online site (www.sealedenvelope.com).

Blinding (investigator's opinion)

Double blinded

Blinding description

Unique codes, which is generated by the software, will be used on the drug boxes. By entering each individual into the study based on the produced sequence, the drug box in which the code is registered, will be assigned to the individual. During the research, the randomization list is held by the statistic consultant, and the participants, the project implementer and all those who participate in the measurement of the indicators will not be aware of the assigned groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahvaz Jundishapur University of Medical Sciences

Street address

Golestan Road

City

Ahvaz

Province

Khouzestan

Postal code

6135733184

Approval date

2018-02-17, 1396/11/28

Ethics committee reference number

IR.AJUMS.REC.1396.1001

Health conditions studied

1

Description of health condition studied

Gingivitis

ICD-10 code

K05

ICD-10 code description

Gingivitis and periodontal diseases

Primary outcomes

1

Description

Gingival index

Timepoint

Start intervention and a month later

Method of measurement

Silness & Loe Index

2

Description

Plaque index

Timepoint

Start intervention and a month later

Method of measurement

Silness & Loe Index

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Persica mouth wash 3 times a day for 1 months

Category

Treatment - Drugs

2

Description

Intervention group: Chamomile mouth wash 3 times a day for 1 months

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Golestan Hospital in Ahvaz

Full name of responsible person
Amir Siahpoosh

Street address
Medicinal Plants Research Center and Deparment of Pharmacognosy, Faculty of Pharmacy, Ahvaz Jundishapur University of medical Sciences, Ahvaz, Iran

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6135733118

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Email
golestanhospital@ajums.ac.ir

Web page address
http://golestan.ajums.ac.ir/rha/mataleb/dasteh/39

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences, medicinal plants research center

Full name of responsible person
Dr Mohamad badavi

Street address
Ahvaz golestan road

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6135733184

Phone
+98 61 3336 2414

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amirsiahpoosh@yahoo.com

Grant name

Grant code / Reference number

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

Title of funding source
Ahvaz Jundishapur University of Medical Sciences, medicinal plants research center

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
Ahvaz University of Medical Sciences

Full name of responsible person
Amir Siahpoosh

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

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Person responsible for scientific inquiries

Contact

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Ahvaz University of Medical Sciences

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Person responsible for updating data

Contact

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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

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Only a part of the data will be shared

When the data will become available and for how long

The access period will be 6 months after the publication of the results

To whom data/document is available

The obtained data from current study will be available only for researchers working in academic and scientific institutions.

Under which criteria data/document could be used

Six months after the publication of this study papers, the obtained data will be available to the applicant researchers for further analysis

From where data/document is obtainable

Applicants can be contacted with corresponding author by e-mail

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

Applicants will be able to access the obtained data from current study by sending an email to the corresponding author up to one month

Comments