

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Evaluation of the effectiveness of new herbal mouthwash, Hasis on periodontal indices in patients with plaque induced gingivitis: clinical trial

Protocol summary

Study aim

Determination of the Effect of New Herbal Mouth wash, Hasis as Adjunct Treatment in Gingivitis Patients

Design

Clinical trials with control group, double blind, number of patients: 25, phase 3

Settings and conduct

On the days 0 and 14, the examiner measured the indexes in the dentistry department's Pario section. Double blind The patient did not know which mouthwash was measured The analyst did not know what data was being analyzed for which mouthwash

Participants/Inclusion and exclusion criteria

Inclusion criteria: Dentistry student in shahid beheshti university with plaque induced gingivitis. Exclusion criteria: Pregnant patient- smoking- patient with systemic disease and diabetes- using iron supply- orthodontics therapy

Intervention groups

There were two samples in each patient (the study was cross-over and randomly assigned a mouthwash to be given at first to each group, in the second stage mouthwashes have changed) 1 - Intake of mouthwash 2 - Intake of chlorhexidine On Day 0, the indexes are measured and the first mouthwash is given to the patient, then the indices associated with the first mouthwash are measured on day 14, then the patient does not use any mouthwash for 2 weeks, then the second mouthwash is given to the patient. And the indicators are measured at days 0 and 14

Main outcome variables

Bleeding on probing. Gingival index. Peridontal Probing Depth. plaque index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180131038572N1**
Registration date: **2019-01-24, 1397/11/04**
Registration timing: **retrospective**

Last update: **2019-01-24, 1397/11/04**

Update count: **0**

Registration date

2019-01-24, 1397/11/04

Registrant information

Name

Atiyeh Farahi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

atiyehfarahi1993@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-06, 1396/06/15

Expected recruitment end date

2018-09-06, 1397/06/15

Actual recruitment start date

2018-09-06, 1397/06/15

Actual recruitment end date

2018-12-21, 1397/09/30

Trial completion date

2018-12-21, 1397/09/30

Scientific title

Evaluation of the effectiveness of new herbal

mouthwash, Hasis on periodontal indices in patients with plaque induced gingivitis: clinical trial

Public title

Evaluation of herbal mouthwash, Hasis on plaque induced gingivitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Dentistry student in Shahid Beheshti University with plaque induced gingivitis

Exclusion criteria:

Pregnant patient smoking patient with systemic disease and diabetes using iron supply orthodontics therapy

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyst

Sample size

Target sample size: **25**

More than 1 sample in each individual

Number of samples in each individual: **2**

using Hasis and chlorhexidine mouthwash, cross over

Actual sample size reached: **25**

More than 1 sample in each individual

Actual sample size in each individual: **2**

using Hasis and chlorhexidine mouthwash, cross over

Randomization (investigator's opinion)

Randomized

Randomization description

Using the coin method, the subjects were divided into two groups A and B, Group, and accordingly, the mouthwash was first assigned to each group. Then, in the second stage, by cross over method mouthwashes have changed.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient did not know which mouthwash was used. Mouthwashes were blown in opaque bottles of the same type, labeled A and B. Hasis was flavored with mint (Mint did not have a curative effect on the mouthwash, it was purely flavoring), resulting in a great deal of taste with chlorhexidine. The analyst did not know what data was being analyzed for which mouthwash. Data was provided to the analyzer in the form of mouthwash data A and mouthwash data B.

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti Dental School

Street address

Shahid Beheshti Dental School, Velenjak St. , Shahid Chamran Highway, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1983969411

Approval date

2017-12-19, 1396/09/28

Ethics committee reference number

IR.SBMU.RIDS.REC.1396.553

Health conditions studied

1

Description of health condition studied

plaque induced gingivitis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

periodontal probing depth

Timepoint

On days 0 and 7, use mouthwash

Method of measurement

Measure the gap between the gingival edge to the depth of the envelope by Williams Probe

2

Description

bleeding on probing

Timepoint

On days 0 and 7, use mouthwash

Method of measurement

The presence or absence of bleeding after examination with the Williams probe by observation

3

Description

plaque index

Timepoint

On days 0 and 7, use mouthwash

Method of measurement

The colored surfaces visible after application of the detector solution. o'leary index: number of painted surfaces based on the presence of plaque / number of checked levels x100

4

Description

Gingival Index

Timepoint

On days 0 and 7, use mouthwash

Method of measurement

By Observation and probing

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:Mouthwash Formulated by Shahid Beheshti Pharmaceutical Faculty. Using for 2 weeks. Once upon a time 2 times. For 1 minute 30 minutes after brushing in the morning and night

Category

Treatment - Drugs

2

Description

Intervention group:Chlorhexidine consumption is 0.2%. Cross-over, Consume for 2 weeks. Once upon a time 2 times. For 1 minute 30 minutes after brushing in the morning and night

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Pario section ,Shahid Beheshti Dental School

Full name of responsible person

Dr Mohammadreza Talebi

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Shahid Beheshti Dental School, Velenjak St. , Shahid Chamran Highway,Tehran,Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Mohammadreza Safavi

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mohammadreza Talebi

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Latest degree

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Other areas of specialty/work

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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