

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

The Effectiveness Comparison of Aloe vera, Povidone Iodine and Chlorhexidine Mouthwashes in the Treatment of Patients with Gingivitis

Protocol summary

Study aim

Chlorhexidine Mouthwash is known as a Gold_standard treatment of gingivitis, however, many side effects from this Mouthwash have been reported. The aim of this study is to replace Chlorhexidine Mouthwash with Betadine or Aloe vera mouthwash.

Design

Clinical trial without Control Group, with three Parallel Groups, Double-Blind, Randomized, in each Person is controlled by the Same Person, Phase 2 on 27 Patients. SPSS Software was used for Randomization, in which Triple Blocks were randomly selected.

Settings and conduct

The blindness of a Researcher and a Statistical Consultant so that Mouthwashes are delivered with a Label through the Ward Secretary and the Consultant is not Aware of the Names of Mouthwashes in each Group. This Intervention is performed in the Periodontology Department of Kashan Dental School and after qualifying, the eligible Individuals will be evaluated for GI and SBI GBOB Indicators With the Help of a Periodontal Probe and Scaling will be performed for Patients. After A month of using Mouthwash, in the second session, Indicators are measured again. During this month, Patients' use of Mouthwashes will be monitored by Phone. Patients with good Cooperation are also re-evaluated 14 days after the intervention.

Participants/Inclusion and exclusion criteria

People with Gingivitis over 20 years without Bone Resorption: Absence of hyperthyroidism and allergies to Mouthwashes: Have not undergone Periodontal Treatment in the past six months.

Intervention groups

Group A is given Aloe vera Mouthwash, Group B Betadine, and Group C Chlorhexidine. All Patients will be given a medium Toothbrush and Floss along with Hygiene training

Main outcome variables

inflammation of the Gums will be evaluated, using the

Gingival Index; Sulcular Bleeding Index, and Gingival Bleeding on Brushing

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220409054462N1**

Registration date: **2022-05-22, 1401/03/01**

Registration timing: **registered_while_recruiting**

Last update: **2022-05-22, 1401/03/01**

Update count: **0**

Registration date

2022-05-22, 1401/03/01

Registrant information

Name

pouya Foghi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-22, 1401/03/01

Expected recruitment end date

2022-07-06, 1401/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness Comparison of Aloe vera, Povidone Iodine and Chlorhexidine Mouthwashes in the Treatment of Patients with Gingivitis

Public title

The Effectiveness Comparison of Aloe vera, Povidone Iodine and Chlorhexidine Mouthwashes in the Treatment of Patients with inflamed Gums

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

having at least 20 Teeth in the Mouth regardless of Third Molar Bleeding on Probing Having no Sensitivity to the Mouthwashes that exist in the intervention Absence of Periodontitis Absence of Clinical Attachment loss Age over 20 years

Exclusion criteria:

Undergoing Periodontal Treatment in the past 6 months Systemic diseases such as Diabet, Radiotherapy, Cancer and Hyperthyroidism With Mental or Physical Retardation that could have influenced the Oral Hygiene Presence of Periodontal Pockets Pregnancy

Age

From **20 years** old to **55 years** old

Gender

Both

Phase

2

Groups that have been masked

- Investigator
- Data analyser

Sample size

Target sample size: **27**

Randomization (investigator's opinion)

Randomized

Randomization description

The Subjects will be randomly divided into Three Groups receiving Chlorhexidine, Betadine and Aloe vera. Thus, due to the Gradual Referral of Patients and to maintain the Balance of Individuals in Groups, Individuals are randomly selected by Permuted Block Randomization with Triple Blocks. Thus, based on Random Numbers obtained from SPSS Software, one of the Blocks with Sequence of ; CBA, CAB, BCA, BAC, ACB, ABC is selected. The letter A means the Person assigned to the Aloe vera Group, the letter B means the Person assigned to the Betadine Group, and the letter C means the Person assigned to the Chlorhexidine Group. The Mouthwashes are delivered to Patients in Black Bottles with Labels of A, B, and C.

Blinding (investigator's opinion)

Double blinded

Blinding description

The Therapist delivers the Triple Blocks provided by the Software to the Ward Secretary, and the Mouthwashes are delivered to the Patients along with the Label,

following the Blocks, by the Secretary to the Patients. The Statistical Consultant does not know the Names of Mouthwashes in Groups A, B, and C.

Placebo

Not used

Assignment

Parallel

Other design features

Photographs are also taken of patients before and after the intervention, which can help assess how the Gums are healing. It should be noted that Individuals are evaluated to enter the study through Periodontal Risk Assessment software and Individuals with Medium risk and higher are involved in the intervention. both Jaws are examined separately for Indicators.

Secondary Ids

empty

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

Ethics committee of Kashan University of Medical Sciences

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No. 25, West Shahid Amini Nezhad Ave or West Haft dast Ave., Chahar Bagh Bala Ave., Esfahan City

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Province

Isfahan

Postal code

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Approval date

2022-01-26, 1400/11/06

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1400.175

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

Gingivitis

ICD-10 code

K05.1

ICD-10 code description

Chronic gingivitis

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

Determination and Comparison of total and mean Gingival Index score in three Groups receiving Mouthwashes (Aloe vera, Betadine and Chlorhexidine) before and after Treatment.

Timepoint

A month after the intervention

Method of measurement

To measure the Gingival Index by looking at the Gingival soft tissue, a score of zero to three is given to each of the four areas of the Gingival Soft Tissue of each Tooth. The Scores from the four areas of the Tooth are added together and divided by four to obtain a Specific Gingival Index for each Tooth. The average of Gingival Index is obtained by dividing the Total Gingival Index Score of all Teeth by the Number of Teeth. Each score should have several specific characteristics that are different from the other Score so that the Therapist can easily Determine the score. Zero Grade means Normal Gingival Tissue: Pink or Pale Pink, varying degrees of Stippling, Placement of the Gingival margin on the Enamel or at different levels more apical than Cemento Enamel Junction, firm Gingival Tissue when touched by the Periodontal Probe Grade 1 means Mild Inflammation: Mild Discoloration, slightly reddish Gingival margin, slight Swelling, accumulation of colorless Exudate in the Gingival Margin, no Bleeding during Probing Grade 2 means Moderate inflammation: Red or Blue-red Gingival Tissue Color Glossy, increased Gingival margin due to swelling, Bleeding during Probing grade 3 means Severe inflammation: Marked redness and swelling, Sores, tendency to Bleed spontaneously Examination of all Tooth Surfaces for the Gingival Index begins with the upper right Second Molars and continues to the Midline and upper left Second Molars. The order of Examination on the right starts from the Distal and then the Buccal and Mesial are evaluated. The order of Examination on the left starts from the Mesial and then the Buccal and Distal are examined. After examining all three Mesial, Buccal, and Distal Surfaces, evaluation of the Palatal Surface of the Maxillary Teeth starts from the left second Molar. Examination of the Mandible begins at the left second Molar and continues toward the right Second Molar. The order of Examination on the left is first Distal, then Buccal and Mesial, and on the right is first Mesial, then Buccal and Distal, and finally the lingual Surface is evaluated from the Second left Molar. Mild Inflammation Scores range from 0.1 to 1; Moderate Inflammation is from 1.1 to 2 and severe Inflammation is from 2.1 to 3

2

Description

Determining and Comparing Sulcular Bleeding Index score in three Groups receiving Mouthwashes (Aloe vera, Betadine and Chlorhexidine) before and after Treatment

Timepoint

A Month after the intervention

Method of measurement

Factors such as Marginal Gingival and papillary swelling with or without Ulceration, Marginal Gingival and Papillary Discoloration, and Bleeding during Probing are important in determining the Sulcular Bleeding Index score, so that a score of 0 indicates papillae and a Healthy marginal gingiva score of 1 indicates Bleeding during Probing, without Discoloration and swelling of Papillae and Marginal Gums score 2 indicates Discoloration and Bleeding during probing, without

Gingival swelling score 3 related to Discoloration and Bleeding during probing and slight swelling of the Gums A score of 4 indicates Discoloration and Bleeding during probing and marked swelling of the Gums. A score of 5 indicates Discoloration and Spontaneous Bleeding during probing, a marked swelling that may or may not have Ulcer In the study of Sulcular Bleeding Index, each Jaw is examined separately and is divided into three Sextants. In each Sequence, the Buccal and Lingual Gums are examined separately, and each one that received a higher score is considered as the main score of the Sequence and is compared to the main score of the other two Sextants obtained in the same way. In each Jaw, any Sequence that has a higher score will be compared to subsequent Sessions to evaluate the quality of the intervention.

3

Description

Comparison of Bleeding Differences when brushing (Gingival Bleeding on Brushing) in three Groups receiving Mouthwashes (Aloe vera, Betadine and Chlorhexidine), before and after Treatment

Timepoint

A Month after the intervention

Method of measurement

This Indicator is an important Sign for the Presence or Absence of Gingivitis or Periodontitis, and realizing it can increase People's self-awareness about Gum Health and effective and timely Solutions can be adopted for Treatment. This Index is higher in Gingivitis Patients and is associated with inflammatory lesions. In this Study, People are asked about bleeding when brushing before scaling, and the same Question is repeated after the Intervention. If the Patient states in the first Session that there is no bleeding while brushing, the Evaluation will depend on the Sulcular Bleeding Index and Gingival Index.

Secondary outcomes

1

Description

Evaluation and Comparison of Mouthwash Solutions in terms of Complications (Tooth Discoloration, bad Breathing and Irritation) after the intervention.

Timepoint

A month after intervention

Method of measurement

Patients are asked about the feeling of Change in the Taste and Smell of the Mouth or Burning after using Mouthwashes. Also, using Photographs and asking patients, the amount of discoloration of the Teeth is assessed because in the First Session scaling is done for all Patients. And Discoloration of the Teeth after a Month can indicate the Effect of Mouthwashes.

Intervention groups

1

Description

First intervention group: Aloe vera Mouthwash was assigned to this Group. In this study, 120 ml of Aloe vera Mouthwash Syrup produced by the Company of Barij Esans Kashan is used. which contains 2.5 mg of Glaucoma (Sugar of Konjac Plant) in every 5 ml of Syrup and with a concentration of 50%, the rest is composed of Honey. Patients rinse 10 ccs of this Mouthwash once a Day, before going to bed, for one Month, and then pour it out.

Category

Treatment - Drugs

2

Description

Second intervention group: Betadine Mouthwash was assigned to this Group. It is a Solution of Iodine and Polyvinyl Pyrrolidone in Molecular form. A solution of 250 ml of 10% Betadine produced by Behsa Company is used for this purpose. It is then diluted with a graduated Cylinder in a ratio of 9 Water to 1 Betadine to achieve the desired concentration of 1%. Patients rinse 10 ccs of this Mouthwash once a Day, before going to bed, for one Month and then pour it out.

Category

Treatment - Drugs

3

Description

Third Intervention group: Chlorhexidine Mouthwash assigned to this Group is a Cationic Bisbiguanide with a wide range of functions. In this study, a 250 ml Solution produced by Behsa Company with a Concentration of 0.2% is used. To achieve a Dose of 20 mg, Patients are asked to rinse their Mouths with 10 ml of 0.2% Chlorhexidine Mouthwash for 30 seconds for one Month and every Night before Bed and then pour it out.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashan Dental School

Full name of responsible person

Sara Ebrahimi

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3 km of Qotb Ravandi Ave, Pezeshk Blvd.,Kashan City

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Sponsors / Funding sources

1

Sponsor

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Grant name

Grant code / Reference number

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

No

Title of funding source

Kashan University of Science

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

Kashan University of Medical Sciences

Full name of responsible person

Sara Ebrahimi

Position

Assistant Professor

Latest degree

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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