

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Assessment of the effect of local application of Aloe vera gel as a non-surgical adjunctive treatment in patients with chronic periodontitis

Protocol summary

Study aim

The effect of topical application of aloe vera gel in the surgical treatment of chronic periodontitis. Determine and compare the values probing pocket depth, clinical attachment loss, gingival index, and plaque index.

Design

A double-blind randomized clinical trial, sample size 22, as a split-mouth, which is a control and self-test group.

Settings and conduct

Gorgan Dental Clinic, split-mouth procedure with randomized pre-prepared list of half of jaws treated only with scaling and root planing and the other half with scaling and root planing with topical use of aloe vera gel. After that all treated areas will be covered with periodontal dressing for 24 hours. The purpose of periodontal dressing in the control areas is to blind the patient. All parameters will be performed by another clinician with no information on the nature of the patient's received treatment. As a result of which the evaluator will be blinded.

Participants/Inclusion and exclusion criteria

Entry requirements: at least 18 years, having at least 20 teeth, having at least one area with a pocket depth of 4 mm and more in at least two quadrants, having at least one area with clinical attachment loss of 3 mm and more at least two quadrants, necessity of availability. During the research process, having informed consent. Exclusion criteria: systemic disease, aloe vera allergy and its products, systemic or topical antibiotic therapy in the past 3 months, Antioxidants including vitamin C or E in the past 3 months, scaling and root planing treatment in the past 6 months, smoking and alcohol consumption, pregnancy and lactation.

Intervention groups

The procedure is split-mouth so that scaling and root planing can be done for all teeth. The aloe vera gel will then be randomly assigned to the half of patient's jaw (test group).

Main outcome variables

Depth of pocket, Clinical attachment loss, Gingival index, plaque index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191113045428N1**

Registration date: **2019-12-19, 1398/09/28**

Registration timing: **prospective**

Last update: **2019-12-19, 1398/09/28**

Update count: **0**

Registration date

2019-12-19, 1398/09/28

Registrant information

Name

Shaghayegh Vadoudi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 17 3223 1252

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2019-12-21, 1398/09/30

Expected recruitment end date

2620-04-19, 1999/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the effect of local application of Aloe vera gel as an non-surgical adjunctive treatment in patients with chronic periodontitis

Public title

Aloe vera in periodontitis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Being over 18 years old Having at least 20 teeth in the mouth Having at least one area with probing depth of 4 mm or more in at least two quadrants Having at least one area of clinical attachment loss of 3 mm or more in at least two quadrants Necessity to be available during the research process Having informed consent

Exclusion criteria:

The presence of systemic disease affecting periodontal status Sensitivity to aloe vera and its products Receive systemic or topical antibiotic therapy in the past 3 months Antioxidants intake of vitamin C or E in the past 3 months Scaling and root planing treatment in the past 6 months Smoking Alcohol consumption Pregnancy and lactation

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **22**

Randomization (investigator's opinion)

Randomized

Randomization description

The procedure will be split mouth in such a way that randomly with a pre-arranged randomization by random number table list half of the jaw is treated only with scaling and root planing and the other half with scaling and root planing with Topical use of aloe vera gel will be. After gel application, all treated areas will be covered with periodontal dressing for 24 hours. The purpose of periodontal dressing in the test areas is to prevent the saliva from gaining gel and in the control areas to blind the patient.

Blinding (investigator's opinion)

Double blinded

Blinding description

The participant is kept blind as he does not know which quadrant of the jelly is placed because all the parts are put on periodontal dressing. The measuring clinician is kept blind and does not know where the gel is inserted when measuring the parameters.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Golestan University of Medical Sciences

Street address

Dental clinic, Edalat 97 Ave., Naharkhoran Blvd.

City

Gorgan

Province

Golestan

Postal code

4916953358

Approval date

2019-11-11, 1398/08/20

Ethics committee reference number

IR.GOUMS.REC.1398.252

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

Chronic periodontitis is an inflammatory periodontal disease caused by the penetration of germs into the inflamed gums, resulting in periodontal tissue destruction and alveolar bone loss. Chronic periodontitis is the most common form of periodontitis.

ICD-10 code

K05.3

ICD-10 code description

Chronic periodontitis

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

Probing Pocket Depth

Timepoint

Before starting the study, 1 and 3 months later

Method of measurement

Distance of free gingival margin to base of gingival groove by periodontal probe Williams

2**Description**

Clinical Attachment Loss

Timepoint

Before starting the study, 1 and 3 months later

Method of measurement
Distance of Cemento Enamel Junction to base of gingival groove by periodontal probe Williams

3

Description

Gingival Index

Timepoint

Before starting the study, 1 and 3 months later

Method of measurement

Specified number to determine the degree: Gingival Index0 (normal), Gingival Index1 (mild), Gingival Index2 (medium), Gingival Index3 (severe)

4

Description

Plaque Index

Timepoint

Before starting the study, 1 and 3 months later

Method of measurement

Percentage of adherent microbial plaque on tooth surface: Desirable: 0-30 Average: 31-50 Undesirable: 51-100

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Before starting treatment, patients are subjected to the same hygiene training and are asked to use Orchid floss twice a day to clean interdental surfaces, followed by bass technique and Dr.West (soft) tooth brushing and toothpaste Merident Brush their teeth.A week later clinical parameters, measurements and treatment will begin.The procedure will be split mouth.That is, it will be randomly treated with a pre-made randomization list of half of a jaw under scaling and root planing with Aloe vera gel will be treated twice a week with topical application.

Category

Treatment - Drugs

2

Description

Control group: Before starting treatment, patients are subjected to the same hygiene training and are asked to use Orchid floss twice a day to clean interdental surfaces, followed by bass technique and Dr.West (soft) tooth brushing and toothpaste Merident Brush their teeth.A week later clinical parameters, measurements and treatment will begin.The procedure will be split mouth. In the control group the other half of the jaw is treated only with scaling and root planing.In fact, the effectiveness of a substance is measured by each

individual

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Gorgan Dental School

Full name of responsible person

Ida Mirzaei

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

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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

Gorgan 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
Gorgan University of Medical Sciences
Full name of responsible person
Shaghayegh Vadoudi
Position
Student
Latest degree
A Level or less
Other areas of specialty/work
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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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Only part of the information, such as information on the main outcome or the like, can be shared.

When the data will become available and for how long

Start of access period 6 months after publishing results

To whom data/document is available

Professors and Students of Medical Sciences Universities

Under which criteria data/document could be used

No conditions

From where data/document is obtainable

Using the available e-mail

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

If available, the data will be provided to the requested person within 2 months .

Comments