

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Assessment of the effect of local application of Aloe Vera gel as a non-surgical adjunctive treatment in type 2 diabetic patients with chronic periodontitis referring to Gorgan dental school

Protocol summary

Study aim

Determination and comparison of pocket probing depth (PPD), clinical attachment level (CAL), gingival index (GI), microbial plaque index (PI) in type 2 diabetic patients with chronic periodontitis in areas treated with scaling and root planing alone And areas treated with scaling and root planing with local application of aloe vera gel before, 1 and 3 months after treatment.

Design

Randomized clinical trial, with control group, with parallel groups, one-way blind, phase 3 on 44 patients, rand function of Excel software was used for randomization.

Settings and conduct

44 patients with type 2 diabetes with moderate to severe chronic periodontitis and referred to the periodontology department of Gorgan Dental School will be considered as the statistical population. The method is split mouth so that randomly in a quadrant of each patient; s jaw, scaling and root planing with local application of aloe vera gel (test group) and in the opposite quadrant jaw scaling and root planing will be done alone (control group). The purpose of placing periodontal dressing in control areas is to blind the patient.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) Patients with type 2 diabetes 2) Being over 18 years old exclusion criteria: 1) Patients with uncontrolled diabetes (HbA1C> 7) 2) Pregnancy and lactation

Intervention groups

Half of one patient's jaw will be treated only with scaling and root planing (control group) and the other half of the jaw will be treated with scaling and root planing with local application of aloe vera gel (test group).

Main outcome variables

Since there are few similar studies on the application of the topical effect of aloe vera gel in the treatment of periodontal disease and only one similar study has been

performed, further studies can improve the results of this study.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200919048760N1**

Registration date: **2020-09-23, 1399/07/02**

Registration timing: **prospective**

Last update: **2020-09-23, 1399/07/02**

Update count: **0**

Registration date

2020-09-23, 1399/07/02

Registrant information

Name

Iman Zarei sani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-26, 1399/07/05

Expected recruitment end date

2020-12-25, 1399/10/05

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 a non-surgical adjunctive treatment in type 2 diabetic patients with chronic periodontitis referring to Gorgan dental school

Public title
Assessment of the effect of local application of Aloe Vera gel in treatment of gum inflammation in diabetic patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Type 2 diabetic patients Being over 18 years old Having at least 20 teeth in the mouth Having at least one area with a pocket depth of 4 mm and more and with a loss of clinical attachment of 3 mm and more in four or more teeth in at least two quadrants The need for availability during the research process Having conscious satisfaction
Exclusion criteria:
Receive systemic or topical antibiotic therapy in the last 3 months Consumption of antioxidants including vitamin C or E in the last 3 months Receive scaling and root planing treatment in the last 6 months History of any periodontal treatment, both surgical and non-surgical, during the last 6 months Patients undergoing orthodontic treatment Patients with uncontrolled diabetes (HbA1C> 7) Tobacco consumption alcohol consumption Patients with aggressive periodontitis Pregnancy and lactation

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **44**
More than 1 sample in each individual
Number of samples in each individual: **2**
Half of one patient's jaw will be treated only with scaling and root planing (control group) and the other half will be treated with scaling and root planing with topical application of aloe vera gel (test group).

Randomization (investigator's opinion)
Randomized

Randomization description
The method is split mouth so that randomly with a pre-prepared randomization list in a quadrant of each patient's jaw, scaling and root planing with local application of aloe vera gel (test group) and in the opposite quadrant Jaw scaling and root planing will be done alone (control group).

Blinding (investigator's opinion)
Single blinded

Blinding description
After applying the gel, all treated areas will be covered with periodontal dressing (coe pack) for 24 hours. The purpose of placing periodontal dressings in test areas is to prevent the gel from being washed away by saliva and to create a longer effect. The purpose of placing periodontal dressing in control areas is to blind the patient.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees
1
Ethics committee
Name of ethics committee
Ethics committee of Gorgan University of Medical Sciences
Street address
Faculty of Dentistry, Gorgan University of Medical Sciences, Shahriar Ave 5, Shahriar town
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Golestan
Postal code
4913983635
Approval date
2020-06-14, 1399/03/25
Ethics committee reference number
IR.GOUMS.REC.1399.104

Health conditions studied
1
Description of health condition studied
Type 2 diabetic patients with chronic periodontitis
ICD-10 code
ICD-10 code description

2
Description of health condition studied
Type 2 diabetic patients with chronic periodontitis
ICD-10 code
ICD-10 code description

Primary outcomes
1
Description
probing pocket depth (PPD) in millimeters Clinical

attachment level (CAL) in millimeters Gingival index (GI) in terms of graded determination plaque index (PI) in percentage

Timepoint

The time of measurement of variables is at the beginning of the study (before the intervention), 1 month and 3 months after treatment.

Method of measurement

probing pocket depth (PPD) in millimeters by Williams periodontal probe Clinical attachment level (CAL) in millimeters by Williams periodontal probe. Gingival index (GI) according to the assigned grading: GI0 (normal): Pink gums Normal, non-inflammatory GI1 (mild): Slightly discolored gums, Negative BOP GI2 (moderate): Red, shiny, swollen gums, Positive BOP GI3 (severe): Gums red, swollen, with spontaneous sores and bleeding / Examination with periodontal probe . Plaque index (PI): How to measure PI: (Number of painted surfaces * 100) / (Number of teeth * 4) Percentage: Optimal: 0-30 Medium: 31-50 Unfavorable: 51-100

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The procedure will be in the form of a split mouth in such a way that randomly with a pre-prepared randomization list, half of one patient's jaw is treated only with scaling and root planing (control group) and half The other jaw will be treated with scaling and root planing with local application of aloe vera gel (test group). In the control quadrant, scaling areas and planing of roots and gingival pockets are routinely washed with distilled water. The aloe vera gel used in this study contains 98% pure aloe vera gel obtained from the leaves of the aloe vera plant plus 2% emulsifier. To prepare the gel, first wash the leaves of aloe vera with water and then disinfect them. Remove the green leaf part of the leaf and keep the gel released from it in a sterile container. The emulsifier has no therapeutic properties and its purpose is only to stabilize and maintain the gel state. The gel is inserted passively through an insulin syringe from the base of the periodontal pocket to the marginal edge of the patient's gums without applying any force so that some of the gel leaks out of the gingival margin. One week after the first stage of treatment, the patient will be placed the gel again.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Dentistry, Gorgan University of Medical Sciences

Full name of responsible person

Iman Zarei Sani

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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

Iman Zarei Sani

Position

collegian

Latest degree

A Level or less

Other areas of specialty/work

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Gorgan University of Medical Sciences

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Position

Assistant Professor

Latest degree

Specialist

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Person responsible for updating data**Contact****Name of organization / entity**

Gorgan University of Medical Sciences

Full name of responsible person

Iman Zarei sani

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

Patients' periodontal charts will be published, which include details of the variables.

When the data will become available and for how long

The start of the document access period is a maximum of 1 year after the results are published.

To whom data/document is available

The research documents will be provided to academic researchers.

Under which criteria data/document could be used

The documentation of this study should be used in order to make researchers more familiar with how to record data for further studies.

From where data/document is obtainable

To receive the documents, send a message to Ida.mirzaee65@gmail.com in the name of Dr. Aida Mirzaei.

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

The study documents will be sent to the applicant researcher after verifying his / her identity.

Comments