

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

The Effect of Topical Application of Aloe Vera Gel on IL-1B, IL-17 of Crevicular Fluid in patients with chronic Periodontitis

Protocol summary

Study aim

The Effect of Topical Application of Aloe Vera Gel on IL-1B, IL-17 of Crevicular Fluid in patients with chronic Periodontitis

Design

A randomized controlled clinical trial with parallel, single-blind, randomized groups

Settings and conduct

Patient clinical parameters included plaque index (PI by O'Leary 1972 index), gingival index (GI, Loe & Sillness), and probe depth (PD, by Williams 6-tooth probe) at four dental surfaces (mesial, distal, buccal, and lingual) will be reviewed. Then SRP is done. Each person's mouth is randomly divided (dice throw) into two case and control areas. Aloe vera gel will be injected into the periodontal envelope using an insulin syringe. For the opposite control teeth, distilled water replaces the aloe vera gel. Clinical marker measurements will be performed by an examiner who is blind to the type of treatment. IL-1B and IL-17 will be measured using ELISA kit.

Participants/Inclusion and exclusion criteria

Entrance: Moderate to severe chronic periodontitis, Age 35-50, At least 4 teeth with probe depth of 4 mm in each jaw quadrant, Patients candidate for non-surgical treatment Exit: Allergy to Aloe vera, Use of tobacco, Endodontic and periodontal compound lesions, Periapical lesions, Pregnancy, Severe dental caries, Semi-impacted teeth, Orthodontic patients, Systemic diseases and systemic or topical antibiotic users 6 Months before study, Patients with periodontal disease during the past 6 months and patients receiving periodontal treatment 6 months before study, Patients receiving NSAIDs one month before sampling

Intervention groups

Each person's mouth is randomly divided into two case and control areas. Aloe vera gel will be injected into the periodontal envelope using an insulin syringe. For the opposite control teeth, distilled water replaces the aloe vera gel.

Main outcome variables

Clinical parameters; IL-1B; IL-17

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100412003690N11**

Registration date: **2020-02-06, 1398/11/17**

Registration timing: **prospective**

Last update: **2020-02-06, 1398/11/17**

Update count: **0**

Registration date

2020-02-06, 1398/11/17

Registrant information

Name

Masoomeh Faramarz

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 41 1385 4863

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faramarzim@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-20, 1398/12/01

Expected recruitment end date

2020-04-18, 1399/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The Effect of Topical Application of Aloe Vera Gel on IL-1B, IL-17 of Crevicular Fluid in patients with chronic Periodontitis

Public title
Evaluation of Alvora Gel in Inflammatory Factors in Patients with Periodontitis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Moderate to severe chronic periodontitis Age 35-50
 Have at least 4 teeth with probe depth of 4 mm or more in each jaw quadrant Consent to participate in the study
 Patients candidate for non-surgical treatment
Exclusion criteria:
 Allergy to aloe vera or its products Use of tobacco
 Endodontic and periodontal compound lesions Periapical lesions Pregnancy Severe dental caries Semi-impacted teeth Orthodontic patients Systemic diseases and systemic or topical antibiotic users 6 Months before study
 Patients with periodontal disease during the past 6 months and patients receiving periodontal treatment 6 months before study Patients receiving NSAIDs one month before sampling

Age
From **35 years** old to **50 years** old

Gender
Both

Phase
4

Groups that have been masked

- Outcome assessor

Sample size
 Target sample size: **34**
 More than 1 sample in each individual
 Number of samples in each individual: **2**
 Two areas of the mouth are used as two samples of test and control

Randomization (investigator's opinion)
Randomized

Randomization description
The patients will be randomly divided into two intervention groups using dice throwing and even and odd numbers. The intervention group will be the odd numbers and the control group will be even numbers.

Blinding (investigator's opinion)
Single blinded

Blinding description
All measurements will be performed by an examiner who is blind to the type of treatment

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

International Relations Office, No 2 Central Building, Tabriz University of Medical Sciences, University Street, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Approval date

2020-01-06, 1398/10/16

Ethics committee reference number

IR.TBZMED.REC.1398.1113

Health conditions studied

1

Description of health condition studied

Periodontitis

ICD-10 code

K05.3

ICD-10 code description

Chronic periodontitis

Primary outcomes

1

Description

Plaque Index (PI)

Timepoint

Before entrance in the study and 30 days after initial treatment

Method of measurement

Using the index (O'Leary 1972)

2

Description

Gingival Index (GI)

Timepoint

Before entrance in the study and 30 days after initial treatment

Method of measurement

According to the Loe & Sillness Index

3

Description

Probe depth (PD)

Timepoint

Before entrance in the study and 30 days after initial treatment

Method of measurement

Using Williams probe 6 levels of teeth

4

Description

IL-1B

Timepoint

Before entrance in the study and 30 days after initial treatment

Method of measurement

Using ELISA kit

5

Description

IL-17

Timepoint

Before entrance in the study and 30 days after initial treatment

Method of measurement

Using ELISA kit

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:Aloe vera gel will be injected into the periodontal envelope using an insulin syringe so that the gel enters and fills up to the apical envelope and the gel exits the gingival margin.

Category

Treatment - Drugs

2

Description

Control group: Distilled water will be injected into the periodontal envelope using an insulin syringe so that the water enters and fills up to the apical envelope and exits the gingival margin.

Category

Placebo

Recruitment centers

1

Recruitment center**Name of recruitment center**

Faculty of Dentistry, Tabriz University of Medical

Sciences, Golgasht Ave, Tabriz, IRAN

Full name of responsible person

Masoomeh Faramarzi

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Golgasht Ave, Tabriz

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Samiei

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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

Tabriz 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**

Tabriz University of Medical Sciences

Full name of responsible person

Masoomeh Faramarzi

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Faculty of Dentistry, Tabriz University of Medical Sciences, Golgasht Ave, Tabriz, Iran

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Masoomeh Faramarzi

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for updating data

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Full name of responsible person

Masoomeh Faramarzi

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The data obtained from the participants can be presented in the form of a table. The protocol for the study, which is routine methods, has no problems with its publication. Statistical analysis can also be provided. In this study, an informed consent form will be used that can be published without mentioning the person's name and personal details. A clinical study report can be made after the necessary analyzes.

When the data will become available and for how long

Start the access period 9 months after publishing the results

To whom data/document is available

For researchers in Dental school of Tabriz University

Under which criteria data/document could be used

For scholars working in other academic and academic institutions, if approved by the project implementer

From where data/document is obtainable

Dr. Masoomeh Faramarzi, email or phone Dental school of Tabriz University, Periodontics department, 9144113420 0098 , faramarzim@tbzmed.ac.ir

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

After receiving the request will be answered within a week.

Comments