Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 befor 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

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Masoomeh Faramarzie

Name of organization / entity
Tabriz University of Medical Sciences

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Iran (Islamic Republic of)

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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 befor 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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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