Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Sep 2026

Histological evaluation of clinical effect of topical application of barberries dental gel on the gingival inflammation

Protocol summary

Summary

This study was aimed to evaluate the histological evaluation of the therapeutic effects and the clinical findings of the dental gel that included Berberis on gingival inflammation. In this study, 15 patients referred to the periodontology department of the Mashhad University of Medical Sciences, Iran and suffering from moderate to severe chronic periodontitis (according to AAP classification) were examined. Soft splint was provided for both jaws with the gap in central parts of teeth. Patients were asked to use semi-full splint of Berberis gel on one side and placebo gel on another side of jaw every night for two weeks. PI and GI were measured at the baseline, one and two weeks after intervention. Gum biopsy specimens were also obtained for the histological investigation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138804302216N1**
Registration date: **2009-10-26, 1388/08/04**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2009-10-26, 1388/08/04

Registrant information

Name
Mahboobeh Shabzendedar
Name of organization / entity
Mashhad University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 51 1882 9501
Email address
shabzendedarm@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellery for research, Mashhad University of Medical Sciences

Expected recruitment start date

2008-01-21, 1386/11/01

Expected recruitment end date

2008-10-22, 1387/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Histological evaluation of clinical effect of topical application of barberries dental gel on the gingival inflammation

Public title

Histological evaluation of clinical effect of topical application of barberries dental gel on the gingival inflammation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients suffering from moderate to severe chronic periodontitis (according to AAP classification) referred to the Periodontology, Department of Mashhad University of Medical Sciences, Iran. Exclusion criteria: Presence of immunodeficiency, presence of diabetes, consumption of antibiotic during 3 months prior to study, using antibacterial mouth rinse, use of contraceptive drugs, presence of hematologic disorder, smoking

Age
No age limit
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **15**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Mashhad University of Medical Sciences
Street address
Ghoreishi building, Mashhad University of Medical Sciences, Daneshgah St,
City
Mashhad
Postal code
Approval date
empty
Ethics committee reference number
87023

Health conditions studied

1

Description of health condition studied
Periodontitis
ICD-10 code
K05.3
ICD-10 code description
Chronic periodontitis complex

Primary outcomes

1

Description
Improvement of gingivitis
Timepoint
Two week after use of test gel
Method of measurement
Surgery area and gum-biopsy specimens were obtained for the histological investigation.

Secondary outcomes

empty

Intervention groups

1

Description
Placebo gel, in soft splint, every night for two weeks
Category
Treatment - Drugs

2

Description
Berberin gel, in soft splint, every night for two weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Periodentology deprtment of Mashhad Dental School
Full name of responsible person
Dr Moeen Taghavi
Street address
Periodentology department, Dental School, Vakil abad Ave.
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellery for research, Mashhad University of Medical Sciences
Full name of responsible person
Abass Makarem
Street address
Ghoreishi building, Daneshgah St., Vice chancellery for research, Mashhad University of Medical Sciences
City
Mashhad
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source

Vice chancellery for research, Mashhad University of Medical Sciences

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Dental School

Full name of responsible person
Mahboobeh Shabzendedar

Position
Assistant professor

Other areas of specialty/work

Street address
Pediateric Department, Dental school, Vakil abad Ave

City
Mashhad

Postal code
91775-984

Phone
+98 51 1882 9501

Fax

Email
shabzendedarm@mums.ac.ir

Web page address
www.mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Abass Makarem

Position
Professor

Other areas of specialty/work

Street address
Pediateric Department. Dental School , Vakil abad Ave

City
Mashhad

Postal code
91775-984

Phone
+98 511882950115

Fax
+98 51 1842 0305

Email
makarema@mums.ac.ir

Web page address
www.mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Dental School

Full name of responsible person
Mahboobeh Shabzendedar

Position
Assistant Professor

Other areas of specialty/work

Street address
Pediateric Department, Dental School, Vakil abad Ave.

City
Mashhad

Postal code
91775-984

Phone
+98 51 1882 9501

Fax

Email
shabzendedarm@mums .ac.ir

Web page address
www.mums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty