

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Determine and compare the effects of topical curcumin nanoparticles and chlorhexidine gel on gingival inflammation in chronic gingivitis

Protocol summary

Summary

To determine the effects of topical curcumin Nano gel and chlorhexidine Mouthwash on gingival inflammation in chronic gingivitis on 40 patients, both men and women and has no age limit. In this clinical trial, double-blind, phase 3 trials are study. Inclusion criteria: Having public health, without the need for antibiotic prophylaxis, non-pregnant, non-use of anti-inflammatory substances within six weeks ago and at the time of check Output criteria: Systemic diseases, allergy to any drug in medical history, especially turmeric, periodontitis Participants were randomly divided into two groups of 20 persons (20 tests, 20 people controls) After Scaling and root planning of test group, we measure the index of GI, BOP and PI and then volunteers receive topical curcumin Nano gel 1% and they use it twice a day for 2 weeks (For 1 minute put gel on the gums) Then two weeks later and one month later the indicators PI, GI and BOP were measured. After scaling and root planning of control group, we measure the index of GI, BOP and PI and then receiving 0.2% chlorhexidine should be used twice a day for two weeks.) Each time, 30 seconds in the mouth and then spit out turn (Then two weeks later and one month later the indicators PI, GI and BOP were measured. At the beginning of the study, Scaling and root planning is done for all volunteers. (In order to simulate the conditions volunteers) A health kit is the same as that of gel or mouthwash test and it is said that they do not use any other products during the study. Executive is not aware of volunteers Health kits. Volunteers are not aware that they are in the test group or control. Health Kit contents will be determined at the end of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017012832231N1**

Registration date: **2017-02-07, 1395/11/19**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-02-07, 1395/11/19

Registrant information

Name

Aynaz Alidadiani

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3806 7224

Email address

alidadiania901@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2016-11-10, 1395/08/20

Expected recruitment end date

2016-12-10, 1395/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determine and compare the effects of topical curcumin nanoparticles and chlorhexidine gel on gingival inflammation in chronic gingivitis

Public title

Determine and compare the effects of topical curcumin nanoparticles and chlorhexidine gel on gingival inflammation in chronic gingivitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:A public health; Being without antibiotic prophylaxis; Non-use of anti-inflammatory substances within six weeks ago and at the time of check; Do not use medications such as antihistamines, antidepressants or analgesics within six weeks ago at the time of review; none pregnant Exclusion criteria:Pregnant or lactating mothers; Systemic Disease; Allergy to any drug in medical history, especially of turmeric periodontitis

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad university of medical science

Street address

College of Dentistry,opposite Mellat Park, beginning in Vakil Abad Boulevard, Mashhad

City

Mashhad

Postal code

Approval date

2016-10-19, 1395/07/28

Ethics committee reference number

IR.mums.sd.REC.1394.162

Health conditions studied

1

Description of health condition studied

gingivitis

ICD-10 code

K05.1

ICD-10 code description

Chronic gingivitis

Primary outcomes

1

Description

Plaque index

Timepoint

After SRP , 2 weeks later and a month later

Method of measurement

Eye determining PI

2

Description

GBI

Timepoint

After SRP , 2 weeks later and a month later

Method of measurement

Eye determining GBI

3

Description

BOP

Timepoint

After SRP , 2 weeks later and a month later

Method of measurement

Eye determining BOP by Periodontal Probe

Secondary outcomes

empty

Intervention groups

1

Description

Nano Gel topical curcumin At a dose of 1% twice a day for 1 minute

Category

Treatment - Drugs

2

Description

Chlorhexidine 0.2% Twice daily mouthwash for 30 seconds

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad University of Medical Sciences

Full name of responsible person

Dr Kazem Fatemi

Street address

College of Dentistry, opposite Mellat Park, beginning in Vakil Abad Boulevard, Mashhad

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Kazem Fatemi

Street address

College of Dentistry, opposite Mellat Park, beginning in Vakil Abad Boulevard, Mashhad

City

Mashhad

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source**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

2

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

DR Majid Reza Mokhtari

Street address

College of Dentistry, opposite Mellat Park, beginning in Vakil Abad Boulevard, Mashhad

City

Mashhad

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source**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

Mashhad University of Medical Sciences

Full name of responsible person

Dr Kazem Fatemi

Position

Periodontist/Associate Prof

Other areas of specialty/work**Street address**

College of Dentistry, opposite Mellat Park, beginning in Vakil Abad Boulevard, Mashhad؛رر

City

Mashhad

Postal code**Phone**

+98 51 3806 7224

Fax**Email**

fatemik@mums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Kazem Fatemi

Position

Periodontist/Associate Prof

Other areas of specialty/work**Street address**

College of Dentistry, opposite Mellat Park, beginning in Vakil Abad Boulevard, Mashhad؛رر

City

Mashhad

Postal code**Phone**

+98 51 3806 7224

Fax**Email**

fatemik@mums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Kazem Fatemi

Position

Periodontist/Associate Prof

Other areas of specialty/work**Street address**

College of Dentistry, opposite Mellat Park, beginning
in Vakil Abad Boulevard, Mashhad

City

Mashhad

Postal code

9177948959

Phone

+98 51 3806 7224

Fax

+98 51 3882 9500

Email

fatemik@mums.ac.ir

Web page address

<http://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