

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Effect of oral Nano curcumin on inflammation of gum in patients with gingivitis and slight periodontitis referred to dental school of Guilan university of medical sciences in 1396-97 .

Protocol summary

Study aim

The aim of this study is to find a herbal alternative to reduce inflammation in patients with generalized gingivitis and mild periodontitis .

Design

Two arm parallel groups randomized clinical trial , double blinded , 48 patients .

Settings and conduct

Patients referring to the dental faculty of guilan university of medical science are chosen by expert professor if they satisfied the inclusion criteria . prior to the phase 1 (scaling root planning) , patient are asked to use capsule for 4 weeks ,one time a day after breakfast and then the SRP is conducted .

Participants/Inclusion and exclusion criteria

The average age 16 to 50 years ,generalized gingivitis , Existence of at least 20 teeth in mouth , probing depth 3 mm or less , mild periodontitis with 1 to 2 mm CAL are inclusion criteria .Allergic reaction to curcumin , History of gallstones and obstruction of the biliary tract , People with increased gastric acidity or gastrointestinal ulceration , People who received antibiotic or any other drug in last 3 months , Pregnancy and breastfeeding , Patients with systemic diseases and immuno-suppressants diseases , Liver diseases , Concomitant use of anticoagulant drugs , The patient needs emergency and urgent treatment , Receiving periodontal treatment in last 6 months , Existing orthodontic treatment , Consuming tobacco are excluded criteria from the study .

Intervention groups

Patients are divided into 2 groups . one group receiving oral nano curcumin and the other one receiving placebo .

Main outcome variables

Reduction in papillary bleeding index , Modified gingival index and plaque index after 4 weeks of consuming nano curcumin capsule .

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180416039327N2**

Registration date: **2019-04-01, 1398/01/12**

Registration timing: **registered_while_recruiting**

Last update: **2019-04-01, 1398/01/12**

Update count: **0**

Registration date

2019-04-01, 1398/01/12

Registrant information

Name

Meysam Malekzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-29, 1397/10/08

Expected recruitment end date

2019-08-23, 1398/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of oral Nano curcumin on inflammation of gum in patients with gingivitis and slight periodontitis referred to dental school of Guilan university of medical sciences in 1396-97 .

Public title

Effect of oral Nano curcumin in controlling the inflammation of gingiva .

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

The average age 16 to 50 years Existence of at least 20 teeth in mouth generalized gingivitis mild periodontitis with 1 to 2 mm CAL probing depth 3 mm or less

Exclusion criteria:

Allergic reaction to curcumin History of gallstones and obstruction of the biliary tract People with increased gastric acidity or gastrointestinal ulceration People who received antibiotic or any other drug in last 3 months Pregnancy and breastfeeding Patients with systemic diseases and immuno-suppressants diseases Liver diseases Concomitant use of anticoagulant drugs The patient needs emergency and urgent treatment Receiving periodontal treatment in last 6 months Existing orthodontic treatment Consuming tobacco

Age

From **16 years** old to **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data and Safety Monitoring Board

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is conducted using R software by statistician and patients are divided into two groups based on that . to divide people into two groups of 24 person , randomly , first , people are given a number from 1 to 48 , then , with software R version 3.4.3 , they are divided into two random groups .simple randomization method has been used .

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo capsules were made in terms of the appearance and color similar to the intervention group capsules and when prepared , it is packed in very similar packaging .on the box only the letter A or B by statistician is written so that the dentist and the patients are blinded the contents of the capsule inside the box .

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Guilan University of Medical Sciences

Street address

Fouman Saravan ring road , GUMS complex , dentistry university

City

Rasht

Province

Guilan

Postal code

41941-73774

Approval date

2018-12-29, 1397/10/08

Ethics committee reference number

IR.GUMS.REC.1397.361

Health conditions studied**1****Description of health condition studied**

Chronic gingivitis

ICD-10 code

K05.1

ICD-10 code description

Chronic gingivitis

2**Description of health condition studied**

slight generalized chronic periodontitis

ICD-10 code

K05.32

ICD-10 code description

Chronic periodontitis, generalized

Primary outcomes**1****Description**

Generalized gingivitis and slight periodontitis

Timepoint

Baseline and the end of first , second and fourth week after intervention

Method of measurement

Using Papillary bleeding index , Modified gingival index

and Plaque index

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: using 80 mg nano mycele gelatin curcumin capsule with sina-curcumin brand for 4 weeks ,one time a day , after breakfast , in patients with generalized gingivitis and slight periodontitis made by Exir Nano Sina company in Mashhad .

Category

Treatment - Drugs

2

Description

Control group: using placebo capsule for 4 weeks ,one time a day , after breakfast , in patients with generalized gingivitis and slight periodontitis

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental faculty of Guilan University of Medical Science

Full name of responsible person

Arash Ghafoori

Street address

Rasht ,Fuman-Saravan ring road , Gums complex

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dental@gums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Dr Shadman Nemati

Street address

in front of the 17 SHahrivar hospital , Siadati st ,
Namju st

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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

Rasht 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

Rasht University of Medical Sciences

Full name of responsible person

Leila Safarmashaei

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Person responsible for scientific

inquiries

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Meysam Malekzadeh

Position

Assistant 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

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

Data of evaluated index (papillary bleeding index , modified gingival index ad plaque index) will be released

When the data will become available and for how long

7 months after the publication of final results

To whom data/document is available

Anyone can access the data

Under which criteria data/document could be used

In order to conduct similar research , the data will be accessible

From where data/document is obtainable

leila.mashae@gmail.com malekzadeh@gums.ac.ir

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

After sending an email and explaining the similar research they are performing , the data will be accessible in 6 weeks .

Comments