Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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)

Phone

+98 13 3348 6416

Email address

malekzadeh@gums.ac.ir

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 periodontits
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
City
Rasht
Province
Guilan
Postal code
41941-73774
Phone
+98 13 3348 6406
Fax
+98 13 3348 6423
Email
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
City
Rasht
Province
Guilan
Postal code
41941-73774
Phone
+98 13 3333 6394
Fax
+98 13 3333 6395
Email
research@gums.ac.ir
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
Street address
Rasht , Fuman-Saravan ring road ,Gums complex
City
Rasht
Province
Guilan
Postal code
41941-73774
Phone
+98 11 5524 4075
Email
leila.mashaee@gmail.com

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
Dentistry

Street address
Rasht , Fuman-Saravan ring road , Gums complex

City
Rasht

Province
Guilan

Postal code
41941-73774

Phone
+98 13 3348 6406

Fax
+98 13 3348 6423

Email
meymalekzadeh@gmail.com

Person responsible for updating data

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

Street address
Rasht , Fuman-Saravan ring road , Gums complex

City
Rasht

Province
Guilan

Postal code
41941-73774

Phone
+98 11 5524 4075

Email
leila.mashaee@gmail.com

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.mashaee@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