

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Evaluation of the effect of nano-chlorhexidine on clinical parameters in patients with periodontitis.

Protocol summary

Study aim

Studies have shown that the use of local-delivery nanoparticles improves the biological impact of drugs, resulting in faster penetration and greater access, reduced cytotoxicity, drug dosage and, costs. Given the positive effect of chlorhexidine in the treatment of patients with periodontitis and the side effects of conventional methods, we aim to evaluate the effect of chlorhexidine nanoparticles on the clinical parameters of patients with periodontitis.

Design

16 patients are divided into two groups: for control, scaling and root planing are performed. For the case group, we do scaling and root planning for all patients and put the Nano-CHX in the pocket and inform the patient not to consume anything for up to 30 minutes.

Settings and conduct

The study is performed on patients referring to the periodontology department of Dental School of Qazvin University. The practitioner, the statistics consultant and, the patients are blind

Participants/Inclusion and exclusion criteria

The study is a clinical trial on 16 patients with moderate to severe periodontitis.

Intervention groups

After confirming the diagnosis of moderate or severe periodontitis, we perform clinical examinations (PD, BOP, CAL) and remove the supragingival plaque for all of them.

Main outcome variables

probing depth; clinical attachment loss; plaque and BoP index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191115045450N1**

Registration date: **2019-12-03, 1398/09/12**

Registration timing: **prospective**

Last update: **2019-12-03, 1398/09/12**

Update count: **0**

Registration date

2019-12-03, 1398/09/12

Registrant information

Name

mohamad javad karamshahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3365 0315

Email address

mr.karamshahi@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-06, 1398/09/15

Expected recruitment end date

2020-01-05, 1398/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of nano-chlorhexidine on clinical parameters in patients with periodontitis.

Public title

effect of nano-chlorhexidine on treatment of periodontitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients with chronic moderate to severe periodontitis no systemic disease no aggressive periodontitis

Exclusion criteria:

Age

No age limit

Gender

Both

Phase

0

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: 16

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Patients are treated split-mouth and similarly. The information is coded to the researcher and statistical analyzer

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of AJA University of Medical Sciences

Street address

No. 38, Naddaf Ave., Nokhbegan Blvd., Qazvin Town

City

Qazvin

Province

Tehran

Postal code

3415851856

Approval date

2019-04-28, 1398/02/08

Ethics committee reference number

IR.AJAUMS.REC.1398.013

Health conditions studied

1

Description of health condition studied

chronic periodontitis

ICD-10 code

K05.3

ICD-10 code description

Chronic periodontitis

Primary outcomes

1

Description

probing depth

Timepoint

4 weeks later

Method of measurement

periodontal probe

2

Description

clinical attachment loss

Timepoint

4 weeks later

Method of measurement

periodontal probe

3

Description

recession

Timepoint

4 weeks

Method of measurement

periodontal probe

4

Description

plaque and BoP index

Timepoint

4 weeks

Method of measurement

periodontal probe

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: nanochlorhexidine use

Category

Treatment - Drugs

2

Description

Control group: nothing

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Qazvin University of Medical Sciences, Dental School,
Periodontics Department

Full name of responsible person

Mohamad javad Karamshahi

Street address

Qazvin University of Medical Sciences, Dental School,
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Postal code

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

mohamad javad karamshahi

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No. 38, Naddaf Ave., Nokhbegan Blvd., Qazvin Town

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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

Artesh 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

Artesh University of Medical Sciences

Full name of responsible person

mohamad javad karamshahi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available