

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jun 2026

Investigation of the relationship between chlorhexidine mouthwash and nuclear changes in buccal mucosa in people with gingivitis

Protocol summary

Registration timing: **prospective**

Study aim

Evaluation of nuclear changes (karyorexis, karyolysis, micronucleus, broken egg) of buccal mucosal cells after one week of using chlorhexidine mouthwash.

Last update: **2021-03-03, 1399/12/13**

Update count: **0**

Registration date

2021-03-03, 1399/12/13

Design

Study of goal-based clinical trial, historical cohort, single, non-blind, non-random, phase 2-3 on 50 patients, before and after

Registrant information

Name

Nima Nadafpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2256 4571

Email address

n_nadaf@dentaliau.ac.ir

Settings and conduct

To collect data from the interview technique, questions were asked to patients referred to the periodontology department of Tehran Azad Dental School along with completing the information form and sampling with wet swab from the buccal mucosa before and after one week of using chlorhexidine mouthwash and study by light microscopy Will be used after painting

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

50 people with gingivitis who have referred to the Dental Periodontics Unit of Azad University for scaling; No entry of smokers with a history of more than 5 years and more than 20 cigarettes per day that are considered Heavy Smoker; Retroviral, statins containing statins, ..; and no drug addiction; and no employment in high-risk jobs such as the paint industry, etc .; no recent viral disease; Lack of radiation therapy

Expected recruitment start date

2021-04-04, 1400/01/15

Expected recruitment end date

2021-06-05, 1400/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Intervention groups

Chlorhexidine mouthwash %0.2;250 ml;Najoo Co.

Main outcome variables

Micronucleus, karyorrhexis,karyolysis ,broken egg ,Repair Index,before and after using chlorhexidine mouthwash

Scientific title

Investigation of the relationship between chlorhexidine mouthwash and nuclear changes in buccal mucosa in people with gingivitis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180714040460N7**

Registration date: **2021-03-03, 1399/12/13**

Public title

Evaluation of carcinogenicity of chlorhexidine mouthwash on oral mucosa

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Be in the treatment of phase one gingivitis be between 20-30 years old Have gingivitis

Exclusion criteria:

The smoking group includes samples with a history of consumption of more than 5 years and above 20 cigarettes per day that are considered Heavy Smoker criteria for taking certain drugs (such as antiretrovirals, doses containing statins, ..) Drug addiction engaging in high-risk occupations such as the paint industry, etc recent viral illness Undergoing radiotherapy or Less than one year history for radiotherapy

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **50**

More than 1 sample in each individual

Number of samples in each individual: **2**

Sampling with wet water sling from the buccal mucosa of people before and after one week of using chlorhexidine mouthwash

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Faculty of Dentistry, Islamic Azad University, Tehran Branch

Street address

No. 9, Neystan Alley, Pasdaran St., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

19585157

Approval date

2019-06-01, 1398/03/11

Ethics committee reference number

IR.IAU.DENTAL.REC.1398.011

Health conditions studied

1

Description of health condition studied

Carcinogenic effect of chlorhexidine mouthwash

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Micronucleus

Timepoint

Before scaling and one week after using chlorhexidine mouthwash

Method of measurement

Cell count with light microscope with 400 magnification

2

Description

Karyorrexhis

Timepoint

Before scaling and one week after using chlorhexidine mouthwash

Method of measurement

count with light microscope with 400 magnification

3

Description

Karyolysis

Timepoint

Before scaling and one week after using chlorhexidine mouthwash

Method of measurement

count with light microscope with 400 magnification

4

Description

Broken egg

Timepoint

Before scaling and one week after using chlorhexidine mouthwash

Method of measurement

count with light microscope with 400 magnification

5

Description

Repair index

Timepoint

It is calculated after counting nuclear changes

Method of measurement

Mean karyolysis and karyorexia divided by the mean of micronucleus and Broken ag

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: To evaluate the toxicity of chlorhexidine mouthwash and to diagnose its carcinogenicity, chlorhexidine mouthwash 0/2% 250 ml has been prepared by Najo Company and is supposed to refer to 50 patients of who refer to the periodontology department of Azad University of Tehran . Phase one should be treated by rinsing your mouth thoroughly with water before scaling, and a layer of cells is removed from the surface of the buccal mucosa of the mouth with a wet swab and applied to a clean, sterile slide. The slide is placed, then we fix it with spray fix, and then the mouthwash is rotated twice a day and night after brushing, each time 10 ml of solution, by time 30 seconds ,turned in mouth and Then emptied. The second session of treatment, which is one week later, will take the second sample . both samples after the steps of Pap smear and fixation and nucleus staining and dehydration, we will count nuclear changes of micronucleus, karyorexis, karyolysis and broken eggs with light microscopy.then we can judge the result.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Periodontology, Tehran Azad School of Dentistry

Full name of responsible person

Aida Omni

Street address

No. Pasdaran St., Ninth District, No9

City

Tehran

Province

Tehran

Postal code

1946853314

Phone

+98 21 2256 4571

Email

Aidaommii94@gmail.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Arash Azizi

Street address

No9, 9th Neyestan Alley, Pasdaran street, Tehran, Iran

City

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Phone

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Email

N_nadaf@dentaliau.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Islamic Azad University of Tehran

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

Islamic Azad University

Full name of responsible person

Nima Nadaf Pour

Position

Periodontist Assisstant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

No9,9th Neyestan Alley, Pasdaran Street, Tehran, Iran

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Phone

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Email

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Nima Nadaf Pour

Position

Periodontist Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

No9,9th Neyestan Alley,Pasdaran street,Tehran,Iran

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Phone

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Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Aida Omni

Position

Dental student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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No9,9th neyestan Alley,pasdaran street,tehran,iran

City

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Tehran

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Phone

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Email

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

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

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

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

Analytic Code

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

Data Dictionary

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

Title and more details about the data/document

Investigation of the relationship between chlorhexidine mouthwash and nuclear changes Buccal mucosa in people with gingivitis

When the data will become available and for how long

6 mounths after printing the results

To whom data/document is available

All people who needs data

Under which criteria data/document could be used

The analysis that do not damage the outcome of our data analysis are allowed

From where data/document is obtainable

Faculty of Dentistry, Islamic Azad University of Iran

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

Refer to Tehran Azad Dental School and apply there and have access to the data for a maximum of 2 weeks

Comments