

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Evaluation of the release amount of chitosan and the effect of it on the pH of saliva after consuming chitosan-based gum: a clinical trial study

Protocol summary

Study aim

Determination of chitosan release rate in saliva and its effect on saliva pH after consuming chitosan-based chewing gum

Design

Clinical trial without control group, before and after comparison, without blinding and randomization on 30 patients

Settings and conduct

In one day, 2cc saliva sample will be taken from all volunteers before consuming chewing gum and two hours after eating breakfast without any stimulation by spitting method in a closed container. volunteers should brush their teeth immediately after eating breakfast and should not eat, drink or chew gum after that. In order to prevent any undesirable chemical changes saliva samples will be stored in a ice-containing container and will be sent to the Laboratory of Avicenna University within one hour to quantify the amount of chitosan and measure the pH. Then, volunteers will be given a piece of chewing gum containing chitosan and their saliva is collected in 10, 20 and 30 minutes after chewing in the specified falcon tubes for each time.

Participants/Inclusion and exclusion criteria

In this study, 30 students and staff of Hamadan Dental School will be included in the study. In one day, a saliva sample of 2 cc will be taken from all volunteers before consuming chewing gum and two hours after eating breakfast without any stimulation by spitting in a closed container. Candidates should brush their teeth immediately after eating breakfast and should not eat, drink or chew gum after that

Intervention groups

Each volunteer is given a piece of chitosan-containing gum and asked to spit into Falcon tubes designated for each time, once before chewing and then 10, 20, and 30 minutes after chewing the gum. In total, each volunteer will chew a gum for 30 minutes.

Main outcome variables

pH of saliva, Quantification of chitosan released in saliva

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230611058451N1**

Registration date: **2023-07-30, 1402/05/08**

Registration timing: **prospective**

Last update: **2023-07-30, 1402/05/08**

Update count: **0**

Registration date

2023-07-30, 1402/05/08

Registrant information

Name

mohadese shokripour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 1085

Email address

shokripour557@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-15, 1402/06/24

Expected recruitment end date

2023-09-21, 1402/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	Ethics committee of Hamedan University of Medical Sciences
Scientific title	Street address
Evaluation of the release amount of chitosan and the effect of it on the pH of saliva after consuming chitosan-based gum: a clinical trial study	Shahid Fahmideh Blvd. , Pazhouhesh Square
Public title	City
Evaluation of the release amount of chitosan and the effect of it on the pH of saliva after consuming chitosan-based gum	Hamedan
Purpose	Province
Prevention	Hamadan
Inclusion/Exclusion criteria	Postal code
Inclusion criteria:	6517838736
Have good oral hygiene. Have at least 24 healthy teeth (5 teeth in each quadrant of the jaw).	Approval date
Exclusion criteria:	2023-04-08, 1402/01/19
Has antibiotics in the last 6 months. Being a smoker. Using mouthwash. Having systemic disease. Having any sign of periodontal disease. Having an orthodontic device or any prosthesis in his/her mouth.	Ethics committee reference number
Age	IR.UMSHA.REC.1402.022
No age limit	
Gender	
Both	
Phase	
N/A	
Groups that have been masked	
No information	
Sample size	
Target sample size: 30	
More than 1 sample in each individual	
Number of samples in each individual: 4	
Each volunteer is given a piece of chitosan-containing gum and asked to spit their saliva into Falcon tubes designated for each time, once before chewing and then 10, 20, and 30 minutes after chewing the gum. In total, each volunteer will chew a gum for 30 minutes.	
Randomization (investigator's opinion)	
N/A	
Randomization description	
Blinding (investigator's opinion)	
Not blinded	
Blinding description	
Placebo	
Not used	
Assignment	
Single	
Other design features	
Comparison before and after the intervention	
Secondary Ids	
empty	
Ethics committees	
1	
Ethics committee	
Name of ethics committee	

Recruitment centers

1

Recruitment center

Name of recruitment center

Hamedan University of Medical Sciences

Full name of responsible person

Mohadese Shokripour

Street address

Shahid Fahmideh Blvd. , Pazhouhesh Square

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Province

Hamadan

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Email

webda@umsha.ac.ir

Web page address

<https://www.umsha.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Reza Shokoohi

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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

Hamedan University of Medical Sciences

Proportion provided by this source

90

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

2

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

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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

Hamedan University of Medical Sciences

Proportion provided by this source

10

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

Hamedan University of Medical Sciences

Full name of responsible person

Mohadese Shokripour

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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

The amount of chitosan released into saliva and pH of saliva

When the data will become available and for how long

Access starts from 1404

To whom data/document is available

Researchers working in academic, scientific and industrial institutions

Under which criteria data/document could be used

Making chewing gum to reduce the rate of dental caries

From where data/document is obtainable

Hamadan University of Medical Sciences, Faculty of Dentistry or E-Mail

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

At least 2 weeks

Comments