Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jul 2026

Double blinded parallel randomized clinical trial to determine the effect of chewing gum containing Zingiber officale on dry mouth condition in patients under hemodialysis in comparison with chewing gum without Zingibr officale

Protocol summary

Study aim
Comparison of the effectiveness of chewing gum with and without ginger on dry mouth

Design
Clinical trial with control group, with parallel groups , double-blind , randomized , phase 3 on 28 patients. Balanced block randomization method was used for randomization.

Settings and conduct
This study is performed on patients undergoing hemodialysis in the dialysis ward of Imam Khomeini Hospital in Tehran. Patients enter the study after obtaining informed consent and confirmation of dry mouth. Stimulated and non-stimulated saliva of patients is collected before and after the intervention and also questionnaires are provided to assess the quality of life and severity of dry mouth. Patients and the reader will not know the content of chewing gum.

Participants/Inclusion and exclusion criteria
Patients will be selected according to the following inclusion criteria: People of both sexes over 18 years old , Confirmation of dry mouth Exclusion criteria include: Patients who are unable to chew gum due to oral conditions , History of allergic reaction to chewing gum and its contents (including ginger) , Severe cognitive deterioration , Conditions affecting salivary flow rate

Intervention groups
Intervention group: Recipient of 60 gums containing 0.15 g of ginger (formulated by a pharmacologist) for 14 days 4 times a day Control group: Recipient of 60 chewing gums with the same ingredients in the intervention group only without ginger for 14 days 4 times a day

Main outcome variables
Stimulated saliva , Unstimulated saliva , Oral health related quality of life , Severity of dry mouth

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201201049550N1**
Registration date: **2021-01-03, 1399/10/14**
Registration timing: **registered_while_recruiting**

Last update: **2021-01-03, 1399/10/14**
Update count: **0**

Registration date
2021-01-03, 1399/10/14

Registrant information

Name
Fatemeh Dadashi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-12-30, 1399/10/10

Expected recruitment end date
2021-01-30, 1399/11/11

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title

Double blinded parallel randomized clinical trial to determine the effect of chewing gum containing Zingiber officale on dry mouth condition in patients under hemodialysis in comparison with chewing gum without Zingibr officale

Public title

Comparison of the effectiveness of chewing gum with and without Ginger officale on dry mouth condition in patients under hemodialysis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

People of both sexes over 18 years old Confirmation of dry mouth, regardless of the cause, by the standard dry mouth questionnaire, which includes questions related to the amount of saliva in the mouth, swallowing difficulty, a feeling of dryness while eating, the need to drink water while eating, will be examined.

Exclusion criteria:

Patients who are unable to chew gum due to oral conditions History of allergic reaction to chewing gum and its contents , including ginger Severe cognitive deterioration Effective conditions on salivary flow rate : salivary gland aplasia , severe dehydration , chemotherapy , radiation to the head and neck and medications includes : (Tricyclics Anti Deppressants - Tranquiliser - Sedative - Anticoagulants - Antihistamines - Antihypertensive drugs - Antispasmodic and diuretics) - Sjogren's syndrome - Diabetes Mellitus - Sarcoidosis - Human immuno deficiency virus - Hepatitis C - Graft versus Host Disease (GvHD) - Mental Disorders - Primary biliary Cirrhosis - Systemic lupus erythematosus - Rheumatoid arthritis

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **28**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization list will be prepared by a third person who is not involved in the study. The randomization method is the "balanced block randomization" method, in which the people who will participate in the study, in the order of entry into the study, will be divided into blocks whose size is determined by the third person. So, the people in the study remain unaware of the size of the blocks, and this number will remain hidden. And the allocation of each person in each block will be done equally between the two groups by generating random numbers in MS Excel software (e.g., if the block size is 4, in MS Excel software 2 codes A and 2 codes B will be written in 4 rows and a random number will be created in front of each of them and by sorting these 4 rows based on random numbers, the codes (A and B) will be randomly assigned to the members of a given block. This will be done for all other blocks as well. The assignment of codes A and B to the intervention and placebo will be done with a simple random method by a third person and will be reopened after analyzing the data and finalizing the results. The third person will write sequential numbers from one to “n” (sample size) based on the random allocation list on the uniform packages of chewing gum, and thus the participants in the study and the researchers will be unaware of the contents of packages and groupings (even A or B). The random allocation list will be opened after data collection to identify two study groups for statistical analysis.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this intervention, medicated chewing gum and placebo are available and the method of blinding is done in such a way that the gums containing ginger and placebo chewing gum are placed in the same package and are encrypted by a third party and then provided to the participants. Participants, the lead researcher (who is also responsible for patient care) and the data analyzer will not know the content of the gums.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the School of Dentistry, Tehran University of Medical Sciences

Street address

School of Dentistry.,Tehran University of Medical Sciences.,North Kargar End.,Enghelab Sq

City

Tehran

Province

Tehran

Postal code

1477935457

Approval date

2020-07-26, 1399/05/05

Ethics committee reference number
IR.TUMS.DENTISTRY.REC.1399.053

Health conditions studied

1

Description of health condition studied
Xerostomia
ICD-10 code
K11.7
ICD-10 code description
Disturbances of salivary secretion

Primary outcomes

1

Description
Stimulated saliva level
Timepoint
Measurement of stimulated saliva and non-stimulating saliva before the intervention and 14 days after chewing gum
Method of measurement
Measurement of stimulated saliva in milliliters in a plastic vial

Secondary outcomes

1

Description
Unstimulated saliva
Timepoint
Measurement of non-stimulating saliva before the intervention and 14 days after begining the intervention
Method of measurement
Measurement of non-stimulating saliva in milliliters in a plastic vial

2

Description
Oral health related quality of life
Timepoint
Before the intervention and 14 days after the intervention
Method of measurement
Oral Health Impact Profile-14 (OHIP-Per14) questionnaire

3

Description
severity of dry mouth
Timepoint
Before the intervention and 14 days after the intervention
Method of measurement
Xerostomia Inventory (XI) questionnaire (11 questions)

Intervention groups

1

Description
Intervention group: In this study, 60 gums containing ginger formulated by a pharmacist, weighing 1.5 g containing 0.15 g of ginger, are given to the intervention group. The duration of the study will be 14 days. Chewing gum should be chewed at least 4 times a day for 10 minutes during the study.
Category
Treatment - Drugs

2

Description
Control group: In this study, 60 gingerless gums (with the same composition of the intervention group only without ginger) formulated by the pharmacist, weighing 1.5 g, are given to the control group. The duration of the study will be 14 days. Chewing gum should be chewed at least 4 times a day for 10 minutes during the study.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Fatemeh Dadashi

Position
Dental Student

Latest degree
A Level or less

Other areas of specialty/work
Dentistry

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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
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