Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effect of Ginger mouthwash on saliva secretion in hemodialysis patients

Protocol summary

Study aim
Determining the effect of ginger mouthwash on saliva secretion in hemodialysis patients

Design
Clinical trial with intervention and control group without blinding randomized on 90 hemodialysis patients

Settings and conduct
After obtaining the necessary permits and coordinating with the dialysis department of Beheshti Hospital in Hamedan, saliva was collected from patients who meet the entry and exit criteria by a non-stimulating method, then for two weeks, a group of patients was randomly selected. and the other group is given a placebo, and at the end of the first and second week, the volume of saliva is collected in the same way, and their average determines whether the mouthwash has an effect on increasing saliva secretion or not. At the same time as the saliva collection times, a questionnaire related to dry mouth is also given to the patients to measure whether there is a correlation between the score of dry mouth through the questionnaire and a quantitative criterion.

Participants/Inclusion and exclusion criteria
Inclusion criteria criteria for saliva sampling: • It is better for the patients to have no special mental or physical diseases or sensitivity and dry eyes. • The patient should undergo dialysis three times a week and each time for at least 3.5 hours. Exclusion criteria from saliva sampling: • People with diabetes • Pregnant women or people who complain of dry eye disease. • Patients who have undergone radiation therapy (mainly for the treatment of head and neck cancer). • People infected with HIV, hepatitis B or hepatitis C (based on the medical record available in the dialysis department) • Smoking • Allergy to ginger • Refusal to continue cooperation

Intervention groups
Intervention group: administration of ginger mouthwash
Control group: drug administration

Main outcome variables
Determination of saliva secretion

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240812062737N1**
Registration date: **2024-11-14, 1403/08/24**
Registration timing: **prospective**

Last update: **2024-11-14, 1403/08/24**
Update count: **0**

Registration date
2024-11-14, 1403/08/24

Registrant information

Name
Atefe Kahrizi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 87 3552 2501

Email address
a.d.kahrizi96@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-11-27, 1403/09/07

Expected recruitment end date
2024-12-27, 1403/10/07

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Investigating the effect of Ginger mouthwash on saliva secretion in hemodialysis patients

Public title

Investigating the effect of Ginger mouthwash on saliva secretion in hemodialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

It is better for the patients to have no special mental or physical diseases or sensitivity and dry eyes. The patient should undergo dialysis three times a week and each time for at least 3.5 hours.

Exclusion criteria:

Diabetic patients Pregnant women or people who complain of dry eye disease. Patients who have undergone radiation therapy (mainly for the treatment of head and neck cancer). People infected with HIV, Hepatitis B or Hepatitis C (based on the medical record available in the dialysis department) Smoking Allergy to Ginger Refusal to continue cooperation

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

For this purpose, we will use the quadruple block randomization method. For this purpose, we prepare four sheets of paper. We write the letter I meaning "Intervention" on two sheets and the letter C meaning "Control" on the other two sheets. We mix the sheets together and put them in the desk drawer. Upon the referral of each eligible patient, one of the sheets will be randomly drawn and based on this drawn sheet, whether it is I or C, they will be assigned to one of the two intervention groups (the recipient of ginger mouthwash) or control. It should be noted that the drawn cards will not be returned to the drawer until all four cards have been drawn. After randomly pulling out all four sheets, all the sheets are returned to the drawer and the above procedure will be continued for the next four patients until the desired sample size is reached.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamadan University of medical sciences

Street address

Hamadan University of medical science, Shahid Fahmide Boulevards

City

Hamedan

Province

Hamadan

Postal code

6517838678

Approval date

2024-11-09, 1403/08/19

Ethics committee reference number

IR.UMSHA.REC.1403.299

Health conditions studied

1

Description of health condition studied

Salivary secretion rate of hemodialysis patients

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Investigating the effect of ginger mouthwash on salivary glands

Timepoint

The beginning of the study, the end of the first week, the end of the second week

Method of measurement

Quantitative measurement and xerostomia questionnaires

Secondary outcomes

1

Description

The amount of saliva secretion

Timepoint

The beginning of the study, the end of the first week and the end of the second week

Method of measurement

Quantitative measurement using graduated Falcon tube and dry mouth questionnaire

Intervention groups

1

Description
Intervention group: The patient will take mouthwash three times a day for two weeks. Before starting to use the mouthwash, one week later and two weeks later, the saliva volume will be measured and the questionnaire will be filled by the patient, and based on the average result at the end of the first and second week, the effectiveness of the mouthwash will be checked.
Category
Treatment - Other

2

Description
Control group: The patient will take placebo three times a day for two weeks. Before starting to take the placebo, one week later and two weeks later, the saliva volume will be measured and the questionnaire will be filled by the patient, and based on the average result at the end of the first and second week, the effectiveness of the placebo will be checked.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti hosital
Full name of responsible person
Dr. Siamak Daneshvar
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr. Reza Shokouhi
Street address
4th floor, Headquarters of Hamadan University of medical science, Shahid Fahmideh Boulevards
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651783867
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+98 81 3131 4058
Email
Fanavari@umsha.ac.ir
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
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
Hamedan University of Medical Sciences
Full name of responsible person
Atefe Kahrizi
Position
student
Latest degree
A Level or less
Other areas of specialty/work
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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
All data is potentially shareable after de-identifying individuals
When the data will become available and for how long
The access period starts 6 months after the results are published
To whom data/document is available
The data will be available only to researchers working in academic and scientific
Under which criteria data/document could be used
People who intend to use the study data for review articles and meta-analysis
From where data/document is obtainable
Atefe Kahrizi email
What processes are involved for a request to access data/document
After checking the requester's email by Atefe Kahrizi, if the conditions are met, the data will be sent to them 3 days later
Comments