Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2026

Comparison of the effect of curcumin suck able form and ginger mouthwash on oral health and sense of taste in hemodialysis patients

Protocol summary

Study aim
effect of suckable form of curcumin and ginger mouthwash on oral health and sense of taste.

Design
A clinical trial with a control group, with parallel groups, randomized, phase 3 on 99 patients. For randomization, online randomization was used at https://www.sealedenvelope.com.

Settings and conduct
This is a three-group study. The intervention group with curcumin, the intervention group with ginger and the control group, which are conducted in three selected Aja hospitals in Tehran. The patients in the ginger mouthwash group use mouthwash in the morning and at night for 30 seconds to one minute at the rate of 5-10 cc. In the curcumin inhalable form group, patients take 2 40 mg inhalable forms in the morning and 2 40 mg in the evening for one month, and in the control group, no intervention is performed and routine ward care is performed. The BOAS scale and the sense of taste are evaluated in all three groups, before, immediately after the intervention and one month later.

Participants/Inclusion and exclusion criteria
Inclusion criteria include the mental and physical ability to use mouthwash and suction form, the absence of wounds or skin disease in the mouth and face, patients undergoing dialysis. exclusion criteria include using mouthwash or artificial saliva, suffering from acute systemic diseases, suffering from acute oral and dental infection, history of allergy to ginger and turmeric.

Intervention groups
groups of suckable form of curcumin and ginger mouthwash and a control group.

Main outcome variables
oral health and sense of taste

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230625058578N1**
Registration date: **2023-08-18, 1402/05/27**
Registration timing: **registered_while_recruiting**

Last update: **2023-08-18, 1402/05/27**
Update count: **0**

Registration date
2023-08-18, 1402/05/27

Registrant information

Name
Alireza Mohammad hoseini

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
2023-07-23, 1402/05/01

Expected recruitment end date
2024-01-21, 1402/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of curcumin suck able form and ginger mouthwash on oral health and sense of taste in hemodialysis patients

Public title
Investigating the effect of suckable form of curcumin and ginger mouthwash on oral health and sense of taste
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients over 18 years of age Patients who They undergo dialysis three days a week and dialysis adequacy (Kt/V) is normal. Mental and physical ability to use mouthwash and suction form Being healthy and not having wounds or skin disease in the mouth and face area Persons who have a score of more than 6 in the BIOS scale review
Exclusion criteria:
1. Use of anti-inflammatory substances by hemodialysis patients in the past six weeks and at the time of examination Antibiotic use Having immune system deficiency Suffering from blood platelet deficiency Suffering from acute systemic diseases Acute oral and dental infection History of allergy to ginger and turmeric Drug addiction Suffering from mental and cognitive diseases that make it impossible to communicate with the patient Medical problems such as history of radiotherapy, Sjogren's syndrome and the use of drugs that affect salivary glands and their secretion Suffering from diabetes in those seeking help who take the inhaled form of curcumin People whose sense of taste has been lost during another special disease (coronavirus patients, etc.) Using mouthwash or artificial saliva
Age
From **18 years** old to **75 years** old
Gender
Both

Phase
1-2
Groups that have been masked
No information
Sample size
Target sample size: **99**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization is a block randomization in blocks of six, which will be assigned to three intervention groups: ginger mouthwash, curcumin lozenge form, and control group. The randomization unit is individual. The randomization tool is web-based randomization. A block method with a volume of 6 is used to create a random allocation sequence. According to the total number of samples required for the study, which is 99 patients (two intervention groups A, B and control group C), a block of 6 including three groups A, B and C will be randomly designed through the software and then based on the sample size , 99 envelopes (33 envelopes containing paper containing A) and (33 envelopes containing paper containing B and (33 envelopes containing paper C) are prepared. Based on the list of six randomly prepared blocks, a trained person is responsible for allocating patients as It is random, after each patient is admitted to the ward, according to the block of six prepared in the first stage, each patient will be randomly placed in the intervention group (A and B) or the control group (C), and the sample process will be consecutive until the sample is completed. people will be assigned to the desired group in the order of their entry into the study and randomly through randomized blocks. The method of concealment is the use of Sequentially numbered, sealed opaque.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tehran Army University of Medical Sciences
Street address
Pirouzi St. - Abuzar Blvd. - North Rabzah St. - 22 Alley, No. 29, Unit 1
City
Tehran
Province
Tehran
Postal code
1778784644
Approval date
2023-06-19, 1402/03/29
Ethics committee reference number
IR.AJAUMS.REC.1402.063

Health conditions studied

1

Description of health condition studied
oral hygiene
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Oral hygiene
Timepoint
before the intervention, immediately after the intervention and after 1 month after the end of the intervention
Method of measurement
Beck oral health assessment scale

2

Description
sense of taste
Timepoint
before the intervention, immediately after the intervention and after 1 month after the end of the intervention
Method of measurement
Subjective scale of sense of taste

Secondary outcomes

empty

Intervention groups

1

Description
In the intervention group: in the ginger mouthwash group, patients use mouthwash in the morning and at night for 30 seconds to one minute inside the mouth according to the mouthwash instructions, i.e. 5-10 cc. Oral and dental hygiene, including dental floss, how to brush teeth, washing the mouth after every meal, teaching how to use mouthwash and suction form, were taught by the main researcher and the main researcher's associate nurse in the dialysis department, and all clients are asked to They should brush their teeth twice a day, the necessary supervision to do the work is done by the main researcher and through education to the families. None of the participants have dietary restrictions for this study and they continue to eat and maintain oral hygiene according to the routine of dialysis patients. The BOAS scale in each of these two groups is checked before the start of the study and after the completion of the study, after 1 month, and the patients' sense of taste is subjectively asked.
Category
Prevention

2

Description
In the intervention group, the lozenges form of curcumin is used in the form of two in the morning and two in the evening. Oral and dental hygiene includes dental floss, how to brush your teeth, rinsing the mouth after every meal, training in the use of the lozenges form, by the researcher. The principal and the associate nurse of the principal researcher have been trained in the dialysis department and all patients are asked to brush their teeth twice a day. None of the participants have dietary restrictions for this study and they continue to eat and maintain oral hygiene according to the routine of dialysis patients. The BOAS scale in each of these two groups is checked before the start of the study and after the completion of the study, after 1 month, and the patients' sense of taste is subjectively asked.
Category
Prevention

3

Description
Control group: In the control group, no medication is given and the routine care provided to the dialysis patients will continue. None of the participants have dietary restrictions for this study, and according to the routine of the dialysis patients, they continue with nutrition and oral hygiene. . The BOAS scale in each of these two groups is checked before the start of the study and after the completion of the study, after 1 month, and the patients' sense of taste is subjectively asked.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
BESAT hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
dr. mehrabi
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etemadzadeh street, aja university
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tehran
Province
Tehran
Postal code
2309876588
Phone
+98 21 8609 6350
Email
aja@iums.ac.ir
Web page address

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
40
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
foroozeh mehrabi
Position
assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
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assistant professor
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Person responsible for updating data

Contact
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nursing student
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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
Information about the effectiveness of the study includes the effect of the main outcome.
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
Everyone can apply to receive
Under which criteria data/document could be used

Any request is allowed.

From where data/document is obtainable

Information is through email addresses and phone numbers. Mr. Alireza Hosseini 09123054946

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

Send the request by phone or email and check the request by the author and then answer the request to the requester within 72 hours.

Comments