Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

Comparison the effect of mouthwash with pure water and licorice on dry mouth of hemodialysis patients

Protocol summary

Study aim
Comparison the effect of mouthwash with pure water and licorice on dry mouth of hemodialysis patients

Design
A cross over randomized clinical trial study was conducted on witness and control group without blindness

Settings and conduct
This study was a cross-over randomized clinical trial study and the research population is hemodialysis patients referring to the dialysis department of Shahid Hasheminejad Hospital which are in witness and control groups without blindness. The control groups do mouthwash eleven-day with simple water and compare groups with licorice. On the second 11 day, none of the two groups do not do mouthwash. In the third 11 day the control group instead of licorice used water for mouthwash and witness group used licorice instead of water

Participants/Inclusion and exclusion criteria
People with advanced kidney failure undergoing regular hemodialysis (with the same weekly sessions) that complain of dry mouth in the last 4 weeks. Patients should be very alert and have the ability to mouthwash properly, People should not be sensitive to mouthwash, the absence of Sjögren's syndrome is confirmed by a doctor, the absence of systolic blood pressure above 160 mmHg and diastolic pressure above 95 mm Hg, lack of weight gain more than 5% between two sessions of dialysis, do not taking diuretic, Tricyclic antidepressants, Anticholinergic, antihistamine, Anti-angina in the last week.

Intervention groups
Evaluation of the efficacy of oral licorice mouthwash (control group), and mouthwash (Witness group) in advanced kidney failure patients that complain of dry mouth in the last 4 weeks and have the ability to do mouthwash

Main outcome variables
Reducing and removing dry mouth with water and licorice

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180828040890N1**
Registration date: **2018-12-16, 1397/09/25**
Registration timing: **retrospective**

Last update: **2018-12-16, 1397/09/25**
Update count: **0**

Registration date
2018-12-16, 1397/09/25

Registrant information

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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
2018-07-23, 1397/05/01

Expected recruitment end date
2018-08-21, 1397/05/30

Actual recruitment start date
2018-08-01, 1397/05/10

Actual recruitment end date
2018-08-16, 1397/05/25

Trial completion date
2018-09-01, 1397/06/10

Scientific title
Comparison the effect of mouthwash with pure water and licorice on dry mouth of hemodialysis patients

Public title
- Comparison the effect of mouthwash with water and licorice on dry mouth of dialysis patients

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
People with advanced kidney failure undergoing regular hemodialysis (with the same weekly sessions) that complain of dry mouth in the last 4 weeks and have the ability to do mouthwash

Exclusion criteria:
The patient's unwillingness to continue to participate in the study sensitivity to mouthwash licorice. Start medications that cause dry mouth during the study (Antihypertensive, antidepressant, diuretic, anticholinergic, and antihistamine)

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **74**
More than 1 sample in each individual
Number of samples in each individual: **2**
Every person participating in the study does mouthwash eleven-day with simple water and the next eleven days with licorice
Actual sample size reached: **66**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, patients were entered the study by available method and randomly divided into two groups (water, licorice) by block assignment. Thus, the letter A to water, the letter B, is assigned to licorice, and then possible conditions were written on cards and placed on the table. For each group, two of the patients who entered the study according to availability, a replacement card was taken by the researcher and placed in order of letters; the patients were divided in two groups. This process continued until the desired sample size was provided.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Iran University of Medical Sciences

Street address
Hemmat Highway, next to Milad Hospital and Razi congress center, Iran University of Medical Sciences

City
Tehran

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Postal code
۱۴۴۹۶۱۴۵۳۵

Approval date
2017-07-17, 1396/04/26

Ethics committee reference number
IR.IUMS.FMD.REC.1396.9411449005

Health conditions studied

1

Description of health condition studied
Dry mouth

ICD-10 code
R68.2

ICD-10 code description
خشکی دهان

Primary outcomes

1

Description
Thomson questionnaire Oral dry mouth score in 2014

Timepoint
At the study, on the fifth and eleventh day after using water and licorice

Method of measurement
Thomson Oral questionnaire 2014 For dry mouth, 5 questions include: 1- Feeling dry in my mouth 2- When I'm eating, I feel dry in my mouth,3- I have a feeling of dryness in the mouth when eating dry foods,4- I wake up at night for drinking 5- To swallow food, I should eat some water. Each answer is 5 questions using Likert 1- never 2- never ,hardly3- sometimes,4- frequently5- Always and the score of 25 is the highest score which shows the highest levels of dry mouth. And the 5 was lowest score without dry mouth

Secondary outcomes

empty

Intervention groups

1

Description
The intervention group, used licorice and compare group used water at first 11 day. At this time each group used the solution 3 times (half an hour). After a meal, the mouthwash solution was taken and half an hour after the mouthwash, they do not eat anything and do not swallow mouthwash and they are thrown it out of mouth completely. The second 11 day, any mouthwash is used by the two groups. In the third stage of intervention mouthwash solution of two groups is displaced. Intervention group used water and compare group used licorice. Material used was licorice root powder that dissolved 5 grams per 500 cc in water and each time the solution was shaken to form a uniform solution. Licorice root is prepared by the expert of the traditional medicine pharmacist of the Faculty of Traditional Medicine, Dr. Ali Ghobadi, from Tehran's Great Market. In people with regime and absence of three main meals, is done three times mouthwash with an interval of 6-4 hours. Duration of mouthwash was two 11-days for each group and in second 11-day of study mouthwash with water and licorice, each group was completed Thomson's mouthwash questionnaire on fifth and eleventh day of the study

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
بخش دیالیز بیمارستان شهید هاشمی نژاد تهران

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Sponsors / Funding sources

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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
Iran 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
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Nursing student

Latest degree
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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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
The total potential data is being shared in non-identifiable condition
When the data will become available and for how long
After the publication of the paper resulted from the study
To whom data/document is available
Researchers and others
Under which criteria data/document could be used
According to the study
From where data/document is obtainable
Mail to the responsible for the trial update
What processes are involved for a request to access data/document
One week
Comments