Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effect of ice chips and water spray versus drinking liquids on thirst, xerostomia and overweight in patients undergoing hemodialysis: a randomized clinical trial

Protocol summary

Study aim
To assess the effect of ice chips and water spray versus drinking liquids on thirst, xerostomia and overweight in patients undergoing hemodialysis

Design
This is a randomized clinical trial with control group without blinding, phase III, in which eligible patients will be randomly assigned through the block randomization to the intervention and control groups

Settings and conduct
This study will be performed in the Beheshti Hospital in Hamadan city on 90 eligible patients undergoing hemodialysis. The patients will be randomly assigned to the intervention and control groups through the block randomization. Blinding is not possible in this study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 18 to 65 years Being literate Having diabetes and hepatitis B Exclusion criteria: Colds or febrile illnesses Acute oral and dental problems Excess weight more than 5% of dry weight between two dialysis sessions

Intervention groups
Intervention group 1: Consuming ice chips with a volume of 5 ml every time patients feel thirsty until the end of dialysis Intervention group 2: Spray water in the mouth every time patients feel thirsty until the end of dialysis Control group: Consuming water and fluids every time patients feel thirsty until the end of dialysis

Main outcome variables
Primary outcome: Severity of thirst, xerostomia, excess weight

General information

Reason for update
Acronym
IRCT registration information

IRCT registration number: **IRCT20120215009014N459**
Registration date: **2023-02-03, 1401/11/14**
Registration timing: **prospective**

Last update: **2023-02-03, 1401/11/14**
Update count: **0**

Registration date
2023-02-03, 1401/11/14

Registrant information
Name
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-02-20, 1401/12/01
Expected recruitment end date
2023-08-21, 1402/05/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of ice chips and water spray versus drinking liquids

on thirst, xerostomia and overweight in patients undergoing hemodialysis: a randomized clinical trial

Public title
Effect of ice chips and water spray versus drinking liquids on thirst, xerostomia and overweight in patients undergoing hemodialysis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 to 65 years Being literate Having diabetes and hepatitis B
Exclusion criteria:
Colds or febrile illnesses Acute oral and dental problems Excess weight more than 5% of dry weight between two dialysis sessions
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare six sheets of paper, writing on two sheets the name of the intervention 1 and on two other sheets the name of the intervention 2 and on the third two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all six sheets are drawn. The six paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.
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 Hamadan University of Medical Sciences
Street address
Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Province
Hamadan
Postal code
6517838695
Approval date
2022-12-02, 1401/09/11
Ethics committee reference number
IR.UMSHA.REC.1401.945

Health conditions studied

1

Description of health condition studied
Xerostomia
ICD-10 code
R68.2
ICD-10 code description
Dry mouth, unspecified

Primary outcomes

1

Description
Severity of thirst
Timepoint
Before the intervention and after dialysis
Method of measurement
Using Visual Analog Scale (VAS)

2

Description
Xerostomia
Timepoint
Before intervention and after dialysis
Method of measurement
Using standard Xerostomia Inventory

3

Description
Excess weight
Timepoint
Before and after dialysis
Method of measurement
Using weights

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Consuming ice chips with a volume of 5 ml every time patients feel thirsty until the end of dialysis
Category
Treatment - Other

2

Description
Intervention group 2: Spray water in the mouth every time patients feel thirsty until the end of dialysis
Category
Treatment - Other

3

Description
Control group: Consuming water and fluids every time patients feel thirsty until the end of dialysis
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Beheshti Hospital in Hamadan city
Full name of responsible person
Sahar Maleki
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Sponsors / Funding sources

1

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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
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
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Person responsible for updating data

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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