

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 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

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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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	
<u>1</u>	
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	
<u>1</u>	
Description of health condition studied	Xerostomia
ICD-10 code	R68.2
ICD-10 code description	Dry mouth, unspecified
Primary outcomes	
<u>1</u>	
Description	Severity of thirst
Timepoint	Before the intervention and after dialysis
Method of measurement	Using Visual Analog Scale (VAS)
<u>2</u>	
Description	Xerostomia
Timepoint	Before intervention and after dialysis
Method of measurement	Using standard Xerostomia Inventory
<u>3</u>	
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

Street address

Beheshti Hospital, Eram Ave.

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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 Shokoohi

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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

Full name of responsible person

Sahar Maleki

Position

Student of Intensive Cares

Latest degree

Master

Other areas of specialty/work

Nursery

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School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Arezoo Karampourian

Position

Specialist in Health in Disasters and Emergencies

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

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Other areas of specialty/work

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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