

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

Effect of ice chips on thirst, xerostomia and interdialytic weight gain in patients undergoing hemodialysis

Protocol summary

Study aim

Assessing the effect of ice chips on thirst, xerostomia and Interdialytic weight gain in hemodialysis (HD) patients

Design

This study was a single group pretest- posttest study including 49 HD patients.

Settings and conduct

This study was conducted at three dialysis centers including Montserrie, Imam Reza and Hefdahe-Shahrivar in Mashhad

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients who had received hemodialysis treatment, 3 times a week for at least 6 months, age between 18- 65 years, literacy, who are out of the home for less than 8 hours. Exclusion criteria: unwillingness to participate in the study, colds, fever, dental and mouth problems, consumption of angiotensin II inhibitor, diabetes and hepatitis B.

Intervention groups

This was a one- group pretest- posttest study including 49 hemodialysis patients. Instruction was performed at the baseline and patients received face to face instruction. In the fluid stage, patients took fluids only when they felt thirst and recorded their fluid intakes in the checklist. In the ice chip stage, patients received almost half of their required fluid through the use of ice chips and the other half through the use of liquid recorded their fluid and ice intakes in the checklist. the intervals between two dialysis sessions, patients were informed of the intervention and checklist completion was followed up Via SMS .Weight before and after and thirst and xerostomia one time before each dialysis session were measured.

Main outcome variables

Thirst, Interdialytic weight gain, Xerostomia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171230038140N1**

Registration date: **2020-03-02, 1398/12/12**

Registration timing: **retrospective**

Last update: **2020-03-02, 1398/12/12**

Update count: **0**

Registration date

2020-03-02, 1398/12/12

Registrant information

Name

Hajareh Ebrahimi Rigi Tanha

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3721 0483

Email address

ebrahimihajareh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2013-04-05, 1392/01/16

Expected recruitment end date

2013-06-19, 1392/03/29

Actual recruitment start date

2013-04-03, 1392/01/14

Actual recruitment end date

2013-05-30, 1392/03/09

Trial completion date

2013-05-30, 1392/03/09

Scientific title

Effect of ice chips on thirst, xerostomia and interdialytic weight gain in patients undergoing hemodialysis

Public title

Effect of ice chips on thirst, xerostomia and interdialytic weight gain

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

treatment with in-center hemodialysis 3 times weekly for a minimum of 6 months age between 18- 65 years literacy who are less than 8 hours out of the home

Exclusion criteria:

Colds Fever Interdialytic weight gain overweight more than 5% of dry weight Diabetes Hepatitis B Dental and mouth problems Consumption of angiotensin II inhibitor

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **26**

Actual sample size reached: **49**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical committee of Mashhad University of Medical Sciences

Street address

Deputy of Research and Technology; Qureshi Building, Daneshgah street

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2012-11-29, 1391/09/09

Ethics committee reference number

IR.MUMS.REC.1391.704

Health conditions studied

1

Description of health condition studied

Patients undergoing hemodialysis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Thirst

Timepoint

Before each dialysis session

Method of measurement

Dialysis Thirst Inventory (DTI)

2

Description

Interdialytic weight gain

Timepoint

Before and after each dialysis session

Method of measurement

Digital scale

3

Description

Xerostomia

Timepoint

Before each dialysis session

Method of measurement

Xerostomia Inventory (XI)

Secondary outcomes

empty

Intervention groups

1

Description

Instruction was performed in the basic line stage; patients received face to face instruction. In the fluid stage, patients took fluids only when they felt thirst and recorded their fluid intakes in the checklist. In the intervention of the ice chip, patients received almost half of their required fluid through the use of ice chips and the other half through the use of liquid by sucking on ice chips the first time they felt thirsty, and the second time they were thirsty, they drank the liquid and the process continued. This method was chosen as there was no need of depriving patients of having water. Patient

recorded their liquid intake, ice chips and the frequency of feeling thirst in the given checklists and brought them with themselves in the next dialysis session. the intervals between two dialysis sessions, patients were informed of the intervention and checklist completion was followed up Via SMS .Weight before and after, thirst and xerostomia one time before each dialysis session were measured.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Hajareh Ebrahimi Rigi Tanha

Street address

In front of Imam Reza Square-Ibn Sina Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9914786138

Phone

+98 51 3802 2000

Email

ebrahimihajareh@gmail.com

2

Recruitment center

Name of recruitment center

Hefdahe Shahrivar Hospital

Full name of responsible person

Hajareh Ebrahimi Rigi Tanha

Street address

between 14th and 16th Kohsangi- Kohsangi Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9914786138

Phone

+98 51 3840 3015

Email

ebrahimihajareh@gmail.com

3

Recruitment center

Name of recruitment center

Montaserieh Hospital

Full name of responsible person

Hajareh Ebrahimi Rigi Tanha

Street address

In front of the Saba Building; Imam Khomeini 25

Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9914786138

Phone

+98 51 3229 1969

Email

ebrahimihajareh@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Deputy of Research and Technology; Qureshi Building, Daneshgah street

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3841 1538

Email

TafaghodiM@mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Hajareh Ebrahimi Rigi Tanha

Position

Instructors

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Deputy of Research and Technology; Qureshi
Building, Daneshgah street

City

mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3841 1538

Email

ebrahimihajareh@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Hajareh Ebrahimi Rigi Tanha

Position

Instructors

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Deputy of Research and Technology; Qureshi
Building, Daneshgah street

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3841 1538

Email

ebrahimihajareh@gmail.com

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

Mashhad University of Medical Sciences

Full name of responsible person

Hajareh Ebrahimi Rigi Tanha

Position

Instructors

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Deputy of Research and Technology; Qureshi
Building, Daneshgah street

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3841 1538

Email

ebrahimihajareh@gmail.com

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

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable