

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

The effect of ice chips containing menthol on the thirst of patients undergoing dialysis

Protocol summary

Study aim

The effect of ice chips containing menthol on the thirst of patients undergoing dialysis

Design

Randomized controlled clinical trial study- Single blind

Settings and conduct

This clinical trial study will carry out with participation of 60 patients undergoing dialysis referred to dialysis center in Birjand . Participants will be selected by convenient sampling and will be allocated randomly to either experimental (n=30) or control groups (n=30). The experimental group will receive ice chips containing menthol for a week and control group only will receive liquids as usual. Both groups will train on how to complete the check lists, measurement of liquids and fluid intake at intervals between sessions

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 18 and 65 years old, Literacy of reading and writing (at least), 5000 to 10000 White blood cells per Micro-liter, Passing at least 6 month from dialysis, Conducting dialysis three times a week for 3 or 4 hours Exclusion criteria: History of Peritoneal dialysis, History of Kidney transplantation, Axillary temperature above 38.5, common cold, Pregnancy, Oral and dental problems interfering with consuming the ice chips, Smoking, Loss of consciousness, obvious mental or emotional disorders

Intervention groups

Intervention group, will received 12 pieces of ice chips containing menthol (one drop in 500 ml of water) with diameter of 3 cm and density of 0.5 cm daily (that will be provided by the researcher) and Control group will not receive any intervention . In both groups before each dialysis session, questionnaires of dialysis thirst duration, thirst distress of dialysis and thirst severity will be completed in the same condition.

Main outcome variables

Thirst severity, Thirst distress, Thirst duration, Dry mouth, Volume of consumed fluids

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190824044590N1**

Registration date: **2020-08-11, 1399/05/21**

Registration timing: **retrospective**

Last update: **2020-08-11, 1399/05/21**

Update count: **0**

Registration date

2020-08-11, 1399/05/21

Registrant information

Name

morteza abbasi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 56 3266 4751

Email address

morteza.abbasi@bums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2019-10-13, 1398/07/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of ice chips containing menthol on the thirst of patients undergoing dialysis

Public title

The effect of ice chips containing menthol on the thirst of dialysis patients

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 18 and 65 years old Literacy of reading and writing (at least) 5000 to 10000 White blood cells per Micro-liter Passing at least 6 month from dialysis Conducting dialysis three times a week for 3 or 4 hours.

Exclusion criteria:

Peritoneal dialysis Kidney transplantation Axillary temperature above 38.5. Common cold Pregnancy Oral and dental problems interfering with consuming ice chips Smoking Loss of consciousness, obvious mental or emotional disorders

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

patients will be selected through convenience sampling and classified into intervention and control groups based on odd and even days.

Blinding (investigator's opinion)

Single blinded

Blinding description

Blinding in patients is not possible; however the evaluator will not know the intervention type. patients on hemodialysis are randomly classified into two groups in odd and even days

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee, Birjand University of Medical Sciences

Street address

Ghaffari Ave, Birjand Town, Iran

City

Birjand

Province

South Khorasan

Postal code

9717613641

Approval date

2019-05-04, 1398/02/14

Ethics committee reference number

ir.bums.rec.1398.034

Health conditions studied**1****Description of health condition studied**

Chronic renal failure

ICD-10 code

N18.6

ICD-10 code description

End stage renal disease

Primary outcomes**1****Description**

Severity of thirst

Timepoint

Before each dialysis session for one week

Method of measurement

Visual Analogue Scale (VAS)

2**Description**

Thirst distress

Timepoint

Before each dialysis session for one week

Method of measurement

Welch Thirst Distress Scale

3**Description**

Thirst duration

Timepoint

Before each dialysis session for one week

Method of measurement

Thirst duration form (DTI)

4**Description**

Dry mouth

Timepoint

Before each dialysis session for one week

Method of measurement

Dry mouth form (XI)

5

Description

Volume of consumed fluids

Timepoint

Daily

Method of measurement

Checklist

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: patients will receive 12 pieces of ice chips containing menthol (one drop in 500 ml of water) with diameter of 3 cm and density of 0.5 cm daily (that will be provided by the researcher).

Category

Other

2

Description

Control group: patients will not receive any intervention . before each dialysis session, questionnaires of dialysis thirst duration, thirst distress of dialysis and thirst severity will be completed in the same condition

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Dialysis center, Birjand University of Medical Sciences

Full name of responsible person

Fatemeh Khaledi

Street address

Dialysis center, Shahid Beheshti Ave, Birjand, Iran.

City

Birjand

Province

South Khorasan

Postal code

9719873839

Phone

+98 56 3239 3000

Email

khas@bums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Tuba Kazemi

Street address

Ghaffari Ave, Birjand Town, Iran

City

Birjand

Province

South Khorasan

Postal code

9719873839

Phone

+98 56 3244 0388

Email

drtooba.kazemi@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Birjand 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

Birjand University of Medical Sciences

Full name of responsible person

Zahra unesi

Position

Faculty member

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Ghaffari Ave, Birjand Town, Iran

City

Birjand

Province

South Khorasan

Postal code

9719873839

Phone

+98 56 3238 1425

Email

z-unesi@bums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Zahra unesi

Position

Faculty member

Latest degree

Master

Other areas of specialty/work

Nursery

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Province

South Khorasan

Postal code

9719873839

Phone

+98 56 3238 1425

Email

z-unesi@bums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Morteza Abbasi

Position

Master's student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Ghaffari Ave, Birjand Town, Iran

City

Birjand

Province

South Khorasan

Postal code

9719873839

Phone

+98 56 3238 1425

Email

morteza.abbasi@bums.ac.ir

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