

# 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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**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

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Ghaffari Ave, Birjand Town, Iran

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**Province**

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**Postal code**

9719873839

**Phone**

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**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