

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jul 2026

### The effect of cold water spray on thirst distress and dry mouth and Fluid intake in patients with Heart failure

#### Protocol summary

##### Study aim

Determining the effect of cold water spray on thirst distress, dry mouth and fluid consumption in patients with heart failure

##### Design

Clinical trial with a control group, with parallel groups, without blinding, randomized, on 68 patients. For randomization, random blocks of four were used through Random Allocation software.

##### Settings and conduct

The environment of this research was the CCU and heart departments of Imam Reza and Qaim hospitals. Imam Reza hospital includes five CCUs and a heart department, which has a total of 66 active beds, Qaim hospital also has two CCUs and two cardiac departments.

##### Participants/Inclusion and exclusion criteria

Heart failure patients hospitalized in the CCU and heart departments of Imam Reza and Qaim hospitals in Mashhad/ 1- with a diagnosis of heart failure 2- Having limited fluids 3- Age 18 to 65 years 4- At most 24 hours have passed since hospitalization 5- Willingness to participate in the study 6- Not suffering from hearing and speech defects 7- Consciousness 8- Not suffering from psychological diseases 9- Thirst distress scale score above 8 Exclusion criteria: 1- Non-cooperation in the study 2- Failure to fill in the questionnaire 3- Discharge/death of the patient

##### Intervention groups

Intervention / exposure / main outcome group: Heart failure patients hospitalized in the CCU and heart departments of Imam Reza and Qaim hospitals in Mashhad / cold water spray program / reducing the distress of thirst, dry mouth and fluid consumption Control group(s) (placebo, no placebo): Heart failure patients hospitalized in the CCU and heart departments of Imam Reza and Qaim hospitals in Mashhad / department routine

##### Main outcome variables

Thirst distress, dry mouth, fluid intake

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20221229056977N1**

Registration date: **2023-03-16, 1401/12/25**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-03-16, 1401/12/25**

Update count: **0**

##### Registration date

2023-03-16, 1401/12/25

##### Registrant information

##### Name

Amir Ghasemi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3386 5932

##### Email address

ghasemia4001@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-03-11, 1401/12/20

##### Expected recruitment end date

2023-05-10, 1402/02/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of cold water spray on thirst distress and dry mouth and Fluid intake in patients with Heart failure

#### Public title

The effect of cold water spray on thirst distress and dry mouth and Fluid intake in patients with Heart failure

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

1- Diagnosed with heart failure 2- Having limited liquids 3- Age 18 to 65 years 4- At most 24 hours have passed since hospitalization 5- Willingness to participate in the study 6- Not suffering from hearing and speech defects 7- Consciousness 8- Not suffering from psychological diseases 9- Thirst distress scale score above 8

##### Exclusion criteria:

1- Non-cooperation in the study 2- Failure to fill in the questionnaire 3- Discharge/death of the patient

#### 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: **68**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Randomization method: Blocked Random blocks of four through Random Allocation software Allocation concealment method: a closed envelope is used, in such a way that the random sequence generated is printed on cards and stored in the same order inside the closed envelope, whenever a person is found eligible to enter the study, the envelope is opened. and a card is given to him face to face and he is assigned to one of the intervention or control groups based on the card code.

#### 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

Research Ethics Committee of Mashhad University of Medical Sciences

#### Street address

Faculty of Nursing and Midwifery, Doctor's Crossroad, Ibn Sina Street, University of Mashhad, Khorasan Razavi

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

9137913199

#### Approval date

2023-02-28, 1401/12/09

#### Ethics committee reference number

IR.MUMS.NURSE.REC.1401.115

## Health conditions studied

### 1

#### Description of health condition studied

Heart failure

#### ICD-10 code

I50

#### ICD-10 code description

Heart failure

## Primary outcomes

### 1

#### Description

Thirst distress

#### Timepoint

Before the start of the intervention, before each implementation of the cold water spray intervention, the end of the intervention

#### Method of measurement

Thirst distress scale for heart failure patients, numerical rating scale

### 2

#### Description

dry mouth

#### Timepoint

Before the start of the intervention, before each implementation of the cold water spray intervention, the end of the intervention

#### Method of measurement

Challacombe scale, numerical rating scale

### 3

#### Description

Fluid intake

#### Timepoint

Before the intervention, 24 hours later, 48 hours later, 72 hours later

#### Method of measurement

Checklist for registration of consumed liquids

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: The cold water spray program will be implemented 6 times a day every two hours from 9 am to 5 pm for 3 days by the research team. The spray intervention includes different parts of the patient's mouth (upper jaw, lower jaw, left cheek, right cheek and tongue) every time. The water spray is kept in the refrigerator in the department at a temperature of 2 to 8 degrees Celsius.

#### Category

Prevention

### 2

#### Description

Control group: In the control group, the routine method includes wetting the lips when the patient complains of thirst.

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Reza Educational, Research and Treatment Center

##### Full name of responsible person

amir ghasemi

##### Street address

Ibn Sina St., Imam Reza Educational Research and Treatment Center, Mashhad, Razavi, Khorasan

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

##### Phone

+98 51 3854 3031

##### Email

emamreza@mums.ac.ir

### 2

#### Recruitment center

##### Name of recruitment center

Qaim educational, research and treatment center

##### Full name of responsible person

amir ghasemi

##### Street address

Qaim Hospital, Ahmedabad St., Razavi Khorasan

##### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

91766-99199

#### Phone

+98 51 3840 0001

#### Email

b.ghaem@mums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Majid Ghayor

##### Street address

University Street, Qurashi Building, Research and Technology Vice-Chancellor

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9138813944

##### Phone

+98 51 3841 1538

##### Email

vcresraech@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

amir ghasemi

##### Position

University student

##### Latest degree

Bachelor

##### Other areas of specialty/work

Nursery  
**Street address**  
No. 28, 8 Shahid Khani, 37 Shahid Daei Blvd  
**City**  
Mashhad  
**Province**  
Razavi Khorasan  
**Postal code**  
9163844488  
**Phone**  
+98 51 3386 5932  
**Email**  
ghasemia4001@mums.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
Amir Ghasemi  
**Position**  
University student  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Nursery  
**Street address**  
No. 28, 8 Shahid Khani, 37 Shahid Daei Blvd  
**City**  
Mashhad  
**Province**  
Razavi Khorasan  
**Postal code**  
9163844488  
**Phone**  
+98 51 3386 5932  
**Email**  
ghasemia4001@mums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences  
**Full name of responsible person**  
amir ghasemi  
**Position**  
University student  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Nursery  
**Street address**  
No. 28, 8 Shahid Khani, 37 Shahid Daei Blvd  
**City**  
Mashhad  
**Province**  
Razavi Khorasan  
**Postal code**  
9163844488  
**Phone**  
+98 51 3386 5932  
**Email**  
ghasemia4001@mums.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