

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

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Phone

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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

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91766-99199

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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

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Mashhad

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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
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Person responsible for updating data

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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