Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2026

Investigating the effect of implementing a thirst relief program on the thirst in intensive care unit patients

Protocol summary

Study aim
Determining the effect of the implementation of the thirst relief program on the level of thirst of intensive care units patients

Design
This clinical trial has a control group with parallel groups without blinding, with random allocation of samples to groups, which will be conducted on 82 patients hospitalized in special departments. Random allocation will be done using the random sequence generated by the randomization site (www.randomization.com)

Settings and conduct
This clinical trial study without blinding will be conducted on 82 patients of the special care department in Qaim (AS) and Imam Reza (AS) hospitals in Mashhad. During one day from 8:00 am to 8:00 pm in eligible patients, after performing oral care according to the patient's needs, the thirst relief pack includes firstly using a wet swab, then cold water spray (below 4 degrees Celsius) and finally using menthol. (0.1%) will be applied on the lips and every two hours the patient's thirst will be measured with a numerical scale and a thirst scale.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age between 18 and 65 years, Richmond score between +1 - 1, no ulceration in the mouth and lips, being NPO and at least 24 hours stays in the intensive care unit. exclusion criteria: failure to continue cooperation, the occurrence of problems in communication, severe deterioration of the patient

Intervention groups
During one day from 8:00 am to 8:00 pm in eligible patients, after performing oral care according to the patient's needs, the thirst relief pack includes firstly using a wet swab, then cold water spray (below 4 degrees Celsius) and finally using menthol. (0.1%) will be applied on the lips and every two hours, the patient's thirst will be measured with the Numeric and TDS.

Main outcome variables
Thirst intensity; Thirst distress

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220728055572N1**
Registration date: **2022-10-04, 1401/07/12**
Registration timing: **registered_while_recruiting**

Last update: **2022-10-04, 1401/07/12**
Update count: **0**

Registration date
2022-10-04, 1401/07/12

Registrant information
Name
zohreh Rajabzadeh tavil
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 51 3802 2606
Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-09-11, 1401/06/20

Expected recruitment end date
2022-11-21, 1401/08/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Investigating the effect of implementing a thirst relief program on the thirst in intensive care unit patients

Public title

The effect of implementing a thirst relief program on the thirst in intensive care unit patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Proficiency in Persian language Age between 18 and 65 years Having a score of +1 - 1- from the Richmond Irritability-Sedation Scale At least 24 hours of stay in the intensive care unit and 48 hours stay in the ward Not having a history of mental problems according to family members Absence of surgery and wounds in the mouth and lips (based on the oral health form (bedside oral exam) no fluid intake by mouth

Exclusion criteria:

Unwillingness to continue cooperation in conducting research at any stage Changing the patient's state of consciousness so that she is unable to communicate. The occurrence of severe respiratory or hemodynamic disorder so that the patient is unable to continue participating in the study. Any obstacle that causes a delay in the intervention (conducting diagnostic tests outside the department, etc.)

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: **82**

Randomization (investigator's opinion)

Randomized

Randomization description

Closed envelopes: will be placed in closed envelopes after random allocation, and after selecting the research sample, it will come out of the envelope in the allocation package and the individual will be placed in the intervention or control group.

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

Nursing & Midwifery School. Ebnesina Ave., Daneshgah Blvd., mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Approval date

2022-06-11, 1401/03/21

Ethics committee reference number

IR.MUMS.REC.1401.123

Health conditions studied

1

Description of health condition studied

Thirst of patients hospitalized in the intensive care unit

ICD-10 code

R68.2

ICD-10 code description

Dry mouth, unspecified

Primary outcomes

1

Description

Thirst intensity score based on Namrik criteria

Timepoint

from 8 to 20 every two hours (8-10-12-14-16-18-20)

Method of measurement

- Numerical scale (0-10) to measure the intensity of thirst

2

Description

Thirst distress score obtained from the Thirst Distress Scale- Heart Failure

Timepoint

from 8 to 20 every two hours (8-10-12-14-16-18-20)

Method of measurement

Using the Thirst Distress Scale-Heart Failure tool

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group of the thirst relief program will be

implemented. The components of this program are that during one day, from 8:00 am to 8:00 pm, the thirst relief program will be implemented in such a way that at 8:00 am and also at 2:00 pm using the form (bedside oral health exam) Examination of the need for mouthwash and care and necessary measures will be implemented according to the patient's condition and related to thirst and oral hygiene (such as mouthwash) and then from 8:00 am to 8:00 pm every 2 hours, severity and distress Thirst will be evaluated using the Namrik criterion, and if it has a score of 3 or more, the thirst relief pack includes the use of a wet swab first, then cold water spray (below 4 degrees Celsius) and finally the use of menthol (0.1%) on the lips (that the whole intervention will last approximately 5 minutes will be implemented. Also, placing wet gauze on the patient's teeth will be used throughout the study for both control and intervention groups.

Category

Other

2

Description

Control group: At 8:00 am and also at 2:00 pm using the form (Bedside oral exam, oral health examination will be performed to determine the need for mouthwash and the necessary care and care for the patient's condition and related to thirst and oral hygiene (such as mouthwash). and then from 8:00 am to 8:00 pm every 2 hours, the intensity and speed of thirst will be evaluated using the evaluation criteria, and if it has a score of 3 or more, it will be given to care and care will be taken, also from Placing gas in the labia of the patient's teeth will be used throughout the study for both control and intervention groups.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Dr. Mahmoud Mohammadzadeh Shabestri
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2

Recruitment center

Name of recruitment center
Ghaem Hospital
Full name of responsible person
Dr. Gholamali Mamouri
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Fatemeh Hajiabadi
Street address
Nursing & Midwifery School. Ebnesina Ave., Daneshgah Blvd., mashhad
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Web page address
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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
Fatemeh Hajiabadi

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

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Dr. Fatemeh Hajiabadi

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Ph.D.

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Nursery

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

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Person responsible for updating data

Contact

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hajiabadif@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
Yes - There is 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
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
There is currently no plan to publish this data

When the data will become available and for how long
The possibility of accessing the data one year after the end of sampling will be published in the article resulting from the study in approximately 18 months.

To whom data/document is available
The data will be published in the article and will not be for a specific group and will not be presented individually

Under which criteria data/document could be used
The data will be published in the article and will not be for a specific group and will not be presented individually

From where data/document is obtainable
The data will be published in the article and will not be for a specific group and will not be presented individually

What processes are involved for a request to access data/document
The data will be published in the article and will not be for a specific group and will not be presented individually

Comments