

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparing the effect of cold water with mentol and plantago ovata oral care on thirst and dry mouth in intensive care unit patients

Protocol summary

Study aim

Comparison of the effect of mouthwash with cold water, menthol and psyllium ovata on the relief of thirst and dry mouth in patients admitted to intensive care units

Design

Initially, patients who are eligible for the study will be asked if they have a thirst and dry mouth. If their thirst is above 3, they will be included in the study. Then, in one of the groups, cold water will be used with menthol and in the other group of the Psyllium. the intervention will last for a maximum of 15 minutes by the researcher in both groups and will be repeated again 30 minutes later.

Settings and conduct

Medical and surgical intensive care units of Shariati and Imam Khomeini hospitals will form the environment of this study. The intervention will take up to 15 minutes for patients, and intervention will repeat again after at least 30 minutes. Before and after each intervention, the intensity and distress of thirst and mouth dry will be evaluated. The routine interrogation is performed using cotton swabs and chlorhexidine. The control group will receive only routine interventions. Both intervention groups will receive the routine care also.

Participants/Inclusion and exclusion criteria

Age over 18, 24 hours of admission; Ability to understand Persian language; Awareness of time, place and person; Satisfaction to participate in the study; Non-admission of opioids and narcotics ; Richmond criteria between negative one to one; Not having a history of allergy; Thirst more than 3

Intervention groups

Cool water with Menthol: Cold water plus menthol to wash mouth and tongue and menthol to moisturize. plantago ovata (Esfarzah): To wash mouths and tongues, and to wet the lips Control group: Rutin ICU interference with chlorhexidine

Main outcome variables

Thirst intensity : Thirst distress: Dry mouth

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170803035479N2**

Registration date: **2018-11-08, 1397/08/17**

Registration timing: **registered_while_recruiting**

Last update: **2018-11-08, 1397/08/17**

Update count: **0**

Registration date

2018-11-08, 1397/08/17

Registrant information

Name

Leila Sayadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6105 4322

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-23, 1397/08/01

Expected recruitment end date

2019-05-22, 1398/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of cold water with mentol and plantago ovata oral care on thirst and dry mouth in intensive care unit patients

Public title

Comparing cold water with mentol and plantago ovata on thirst and dry mouth

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Age over 18 years old At least 24 hours passed since their admission to the ICU Be able to understand Persian speak and have the ability to read Orientation to time, place and person Willingness to participate in study Do not received drugs such as opioids which suppress the consciousness Richmond criteria between -1 to +1. No history of allergies No history of allergy to the pessilium powder Thirst score more than 3

Exclusion criteria:

Having a open mouth lesions or lips lesions, mouth or lip mucous destroy History of dementia or Alzheimer, interaction of medical condition (like oral surgery) with study intervention

Age

From **18 years** old

Gender

Both

Phase

0

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **132**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to balance the number of samples assigned to each of the treatments in 4 intensive care units, permutation block randomization will be used. Based on this method, we assign randomly the number of patients in each block under the intervention of menthol , plantago psyllium or control. With the help of this intervention allocation method, at the end, the number of patients is equally treated differently and different treatments are equally tested in different parts.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, intervention and data collection will be done by researcher. There will be no possibility to blind researcher, so only participants and statistician will not be aware of the control and intervention groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee**Name of ethics committee**

Institutional research ethics committee school of nursing and midwifery & rehabilitation

Street address

School of Nursing Midwifery ,Tehran University of Medical Sciences Nosrat st. Tohid sq. Tehran I.IRAN

City

Tehran

Province

Tehran

Postal code

141973317

Approval date

2018-09-04, 1397/06/13

Ethics committee reference number

IR.TUMS.FNM.REC.1397.108

Health conditions studied

1

Description of health condition studied

Thirst and dry mouth

ICD-10 code**ICD-10 code description**

Primary outcomes

1

Description

Thirst intensity: Those patients whose thirst scores are greater than three based on numeric rating scales.

Timepoint

Before intervention, immediately after mouth washing for the first time, and also after second mouth washing (30 minutes after first one)

Method of measurement

Numeric rating scales

2

Description

Dry mouth : patient's dryness feeling of lips and mouth

Timepoint

Before mouth washing, after mouth washing for the first time, and also after second mouth washing (30 minutes after first one)

Method of measurement

Patient Self-declaration

3

Description

Distress of Thirst: Feeling sick of thirst

Timepoint

Before intervention, after mouth washing for the first time, and also after second mouth washing (30 minutes after first one)

Method of measurement

Numeric rating scales

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group (cold water with menthol): Oral washing (mouthwash/ oral care) with cold water and menthol is performed in a two-step process in the morning or evening shift. So that for a maximum of 15 minutes, cold water will be rubbed by the researcher to the lips, tongue and mucus Patients' mouths. and the lips of patients will also be moisturized using menthol. At least 30 minutes later, the washings will be repeated with cold water and menthol. Menthol is prepared with a percentage of 0.1 by pharmacist professors from traditional medicine (this will dilute the mint essence in the base of the water). Cool water is used at a temperature of 15-7 ° C for washing the mouth and tongue, and menthol only will use for moisturizing the lips. The menthol is provided with preservatives will last an average of two months in the refrigerator.

Category

Treatment - Other

2

Description

The second intervention group (the plantago ovata/ Esfarzah): The oral washing is done in a two-step process in the morning or evening shift. The prepared solution will last for up to 15 minutes by the researcher on the lips, tongue and oral mucosa of the patients. After 30 minutes, this intervention will be repeated again (The prepared solution will be used both for washing the mouth and tongue, and for wetting the lids). The plantago ovata solution is sprayed at concentration of 0.2 grams (two tenths of gram) in 100 cc of water. The solution will have a preservative that will allow storage in the refrigerator for up to two months. It should be noted that the temperature of the solution is similar to cold water , and both (cold water and Esfarzeh Solution) will have the same temperature. For the preparation of Plantago ovata, the powder of the outer part of the psyllium, which is available at the pharmacy (for the removal of constipation), will be used.

Category

Treatment - Other

3

Description

Control group: A group that only receives routine care

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati hospital, Tehran University of Medical Sciences

Full name of responsible person

Dr. Hamidreza Mehrpoor

Street address

Shariati hospita, Jalal Ahmad StI, Kargar Ave

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Web page address

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2

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Dr Mehrdad Salehi

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Imam Khomeini Hospital , Dr Gharib St, Keshavarz Blvd, Tehran

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Web page address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Mohamad Ali Sahraeiyan

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Tehran University of Medical Sciences Office of Vice-Chancellor for Global Strategies and International Affairs, Number 21, Dameshgh St., Vali-e Asr Ave.

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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

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Elnaz Nasiri

Position

MS Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for updating data

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Other areas of specialty/work

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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