

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effects of nursing interventions on relieving of the patients' intensity and distress of thirsty and dry mouth after coronary artery bypass graft

Protocol summary

Summary

-This random study was done to compare the effect of nursing interventions on reducing the severity and distress of thirst and mouth dryness after coronary artery bypass in cardiac surgery ICU departments. The sample volume will be 80 people. There will be no age limit and the patients will enter the research if they do not have any history of open-heart surgery and background diseases like diabetes. The patients will be randomly divided into two groups of case and control. The control group (20 people) will be intubated and NPO for at least 4 to 6 hours as the routine of surgery department. The case group will get divided into three groups including group A (water spray) (20 people), group B (moisture tissue) (20 people) and group C (sterile ice cubes) (20 people). For group A, 2 milliliters of water is sprayed directly into mouth so that tongue surface and mucous is moist. Gauze is completely moistened with distilled water for group B and it is repeated every 15 minutes. For group C, 2 milliliters of ice is put in patient's mouth if they want. Data is collected through demographic questionnaire, and VAS scale is used to evaluate thirst severity and distress, and type of mouth dryness. The questionnaire is completed based on patients' statements and direct observations 15 minutes after each intervention. Variables of first outcome evaluated in this research include thirst distress, thirst severity, and mouth dryness.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016040227176N1**

Registration date: **2016-08-21, 1395/05/31**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-08-21, 1395/05/31

Registrant information

Name

Ghazal Seif

Name of organization / entity

Hamedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 0583

Email address

gh.seif@edu.umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Hamadan University of Medical Sciences

Expected recruitment start date

2016-07-22, 1395/05/01

Expected recruitment end date

2016-11-21, 1395/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of nursing interventions on relieving of the patients' intensity and distress of thirsty and dry mouth after coronary artery bypass graft

Public title

Thirsty management of Patients after open heart surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Conditions for entering the research: lack of open-heart surgery history; completely able to read and write in Persian; lack of psychological and mental disorders history; not being affected by any background disease like diabetes or renal disease; lack of open wounds or diseases resulting in mouth and lips scaling Conditions of exclusion from the research: heart attack or brain stroke during the study; having another surgery during the study

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 80

Randomization (investigator's opinion)

Randomized

Randomization description

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

Ethics committee of Hamedan University of Medical Sciences

Street address

Hamedan SHaheid Beheshty Blvd, across from People's Park

City

Hamedan

Postal code

Approval date

2016-02-27, 1394/12/08

Ethics committee reference number

IR.UMSHA.REC.1394.529

Health conditions studied

1

Description of health condition studied

R68 Other general symptoms and signs

ICD-10 code

R68.2

ICD-10 code description

Dry mouth, unspecified

Primary outcomes

1

Description

Thirst distress

Timepoint

Every 15 minutes after intervention

Method of measurement

Visual Analogue Scales

2

Description

Thirst severity

Timepoint

Every 15 minutes after intervention

Method of measurement

Visual Analogue Scales

3

Description

Mouth dryness

Timepoint

Every 15 minutes after intervention

Method of measurement

Mouth dryness Form

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: (water spray) 2 milliliters of distilled water (room temperature) is directly sprayed into the mouth by commercially available containers so that tongue surface and mucous is moist. It is performed every 15 minutes.

Category

Other

2

Description

Control group: this group is provided by routine cares and are intubated and NPO at least 4 to 6 hours.

Category

Other

3

Description

Intervention group 2: (ice cubes) 2 milliliters is put in the

patient's mouth. It is done every 15 minutes.

Category

Other

4

Description

Intervention group 3: (moist gauze) the gauze is completely moistened with distilled water and it is repeated every 15 minutes.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Specialist Hospital Heart Farshchian

Full name of responsible person

Ghazal Seif

Street address

Hamedan SHaheid Fahmide Blvd.Specialist Hospital Heart Farshchian

City

Hamedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research and Technology Vice-Chancellor Hamedan University of Medical Sciences

Full name of responsible person

Dr. Saeid Bashirian- Deputy Minister for Research and Technology

Street address

Hamedan, SHaheid Beheshty Blvd-across from People's Park

City

Hamedan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Research and Technology Vice-Chancellor Hamedan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Mahnaz KHatiban

Position

Nursing PhD

Other areas of specialty/work

Street address

Hamedan SHaheid Beheshty Blvd, across from People's Park

City

Hamedan

Postal code

Phone

+98 81 3838 0583

Fax

Email

mahnaz.khatiban@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Mahnaz KHatiban

Position

Nursing PhD

Other areas of specialty/work

Street address

Hamedan SHaheid Fahmide Blvd,across from People's Park

City

Hamedan

Postal code

Phone

+98 81 3838 0583

Fax

Email

mahnaz.khatiban@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Ghazal Seif

Position

Master of Science in Nursing/ nurse

Other areas of specialty/work

Street address

Hamedan SHahied Beheshty Blvd,across from the People's Park

City

Hamedan

Postal code

38698-65178

Phone

+98 81 3838 0583

Fax**Email**

gh.seife@edu.umsha.ac.ir

Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty