

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Effect of salivary gland massage and water spray on Thirst and Xerostomia before heart surgery

Protocol summary

Study aim

Comparison of the effect of salivary gland massage and water spray on thirst and xerostomia before surgery in patients undergoing cardiac surgery

Design

This study was performed on 120 patients who were randomly assigned to two intervention groups and one control group using RANDBETWEEN method in Excel software.

Settings and conduct

Patients are candidates for heart surgery in Afshar Hospital in Yazd. 120 patients with inclusion criteria are randomly assigned to three groups. At seven o'clock in the morning, a questionnaire is completed for all three study groups. For the control group, the questionnaire is completed again one hour later. In the salivary gland massage group, after teaching how to massage, the patient performs the massage process for 3 minutes if he feels thirsty and dry mouth, and an questionnaire is completed again one hour later. In the water spray group, in case of thirst or dry mouth Moisten all the mucous surfaces of the mouth with water spray and then one hour later, the questionnaire is completed again.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Candidate patients for heart surgery
Thirst score and dry mouth one or higher using the visual thirst scale
Exclusion criteria: Sugar more than 126 mg per deciliter in the morning of operation
Chronic dry mouth
Taking anticholinergic drugs, antihistamines, tricyclic antidepressants
Existence of any sores, inflammation or pests in the mouth

Intervention groups

Salivary gland massage intervention group
Water spray intervention group
Control group

Main outcome variables

Thirst, Xerostomia ,Thirst tolerance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210628051732N1**

Registration date: **2021-12-29, 1400/10/08**

Registration timing: **prospective**

Last update: **2021-12-29, 1400/10/08**

Update count: **0**

Registration date

2021-12-29, 1400/10/08

Registrant information

Name

Seyed Tahereh Hosseini Mortazavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3521 4939

Email address

hosseini.mortazavi@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-21, 1400/11/01

Expected recruitment end date

2022-03-20, 1400/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of salivary gland massage and water spray on Thirst and Xerostomia before heart surgery

Public title
Effect of salivary gland massage and water spray on Thirst and Xerostomia

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
patients Candidate for cardiac surgery Age range between 15 to 70 years Thirst and dry mouth score one or more using the visual scale Willingness to participate in the study
Exclusion criteria:
Heart failure (EF less than 35%) Glucose greater than 126 mg / dL on the morning of surgery Chronic dry mouth Dialysis patients Use of anticholinergic drugs, antihistamines, tricyclic antidepressants Tobacco and alcohol abuse Existence of any sores, inflammation or pests in the mouth Candidates for emergency heart surgery

Age
From **15 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, 120 patients who meet the inclusion criteria are selected as a research sample and using the RANDBETWEEN method in Excel software are randomly assigned to two intervention groups and a control group (40 people in each 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
Ethics Committee of Yazd University of Medical Sciences
Street address

Shahid Sadoughi Blvd
City
Yazd
Province
Yazd
Postal code
8917945556
Approval date
2021-03-21, 1400/01/01
Ethics committee reference number
IR.SSU.REC.1399.042

Health conditions studied

1

Description of health condition studied
Thirst
ICD-10 code
T73.1
ICD-10 code description
Deprivation of water

2

Description of health condition studied
Xerostomia
ICD-10 code
k11.7
ICD-10 code description
disturbances of salivary secretion

Primary outcomes

1

Description
Thirst
Timepoint
7 o'clock in the morning on operation day and one hour after
Method of measurement
Visual Analogue Scale (VAS)

2

Description
Xerostomia
Timepoint
7 o'clock in the morning on operation day and one hour after
Method of measurement
Visual Analogue Scale (VAS)

3

Description
Tolerance to thirst and dry mouth
Timepoint
7 o'clock in the morning on operation day and one hour after
Method of measurement

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For the first intervention group, the massage is performed 4 times. The duration of each massage is 3 minutes and it is repeated every 15 minutes.

Category

Rehabilitation

2

Description

Intervention group: For the second group of intervention, water spray at room temperature is used. The volume of water consumed is 70 ml. Water spray is used every 15 minutes.

Category

Rehabilitation

3

Description

Control group: No intervention is performed for the control group.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Afshar Hospital, Yazd

Full name of responsible person

Mohamad Hassan Abdoalahi

Street address

Islamic Republic Boulevard, Yazd

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Yazd

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89179455556

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Afsharhospital@ssu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr. Mostafa Javadi

Street address

Yazd University of Medical Sciences, Bahonar Square

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Afshrhospital@ssu.ac.ir

Web page address

<https://web.ssu.ac.ir/>

Grant name

Grant code / Reference number

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

No

Title of funding source

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Seyede Tahere Hosseini Mortazavi

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Mostafa Javadi
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Yes - There is a plan to make this available

Title and more details about the data/document

The publication of the results will be in accordance with the principle of fiduciary duty and the principle of anonymity of human samples. The general results will be published in the article.

When the data will become available and for how long

Two years

To whom data/document is available

Thesis supervisor, statistical consultant and all researchers at the request and discretion of the dissertation supervisor

Under which criteria data/document could be used

Do similar studies, apply the results in the clinic

From where data/document is obtainable

Scientific responsible for the study

What processes are involved for a request to access data/document

The request will be answered by email within two weeks

Comments