

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 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 a 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

Visual Analogue Scale (VAS)

## 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

##### City

Yazd

##### Province

Yazd

##### Postal code

89179455556

##### Phone

+98 35 3525 5011

##### Email

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

##### City

Yazd

##### Province

Yazd

##### Postal code

8917945556

##### Phone

+98 35 3724 0171

##### Email

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

##### Street address

No. 17, Imam Street, Shahdieh

##### City

Yazd

##### Province

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8943118881

##### Phone

+98 35 3521 4939

**Email**  
hosseini.mortazavi96@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Yazd University of Medical Sciences  
**Full name of responsible person**  
Mostafa Javadi  
**Position**  
Associate professor  
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Ph.D.  
**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

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Yazd University of Medical Sciences  
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**Province**  
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8943118881  
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hosseini.mortazavi96@gmail.com

## 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