

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of two preoperative asepsis methods with 10% Povidone Iodine alone and 10% Povidone Iodine sequences followed by 70% Ethanol on the microbial load of surgery area and bacterial identification in patients who are candidates for open heart surgery

Protocol summary

Study aim

Comparison of the effect of two prep methods with betadine 10% alone and the sequence of betadine 10% and then ethanol 70 ° on the microbial load and mass of the operation site in patients candidates for open heart surgery

Design

Clinical trial with control group, with parallel group, double-blind, simple randomized and on 90 patients

Settings and conduct

This study is a double-blind clinical trial that will be performed on 90 patients who are candidates for open heart surgery at Afshar Hospital of Yazd University of Medical Sciences. This study is designed in such a way that patients do not know the type of medication used to disinfect the operating area and also physicians do not know what group each patient belongs to.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Candidate for heart surgery. No infectious skin diseases. No allergies to antiseptics. People with diabetes Exclusion criteria: The patient's unwillingness to continue cooperation. Negative results of culture before primary prep in both groups

Intervention groups

In all patients, nasal sampling is performed to determine the carriers of Staphylococcus aureus. In one group of patients, 10% betadine sequence and then alcohol are used to disinfect the operative area, and in the other group, only 10% betadine is used. At the end of the operation, deep sampling will be performed in all patients.

Main outcome variables

microbial mass of the operating area and nose, microbial load of the operating area

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201201049562N1**

Registration date: **2020-12-22, 1399/10/02**

Registration timing: **registered_while_recruiting**

Last update: **2020-12-22, 1399/10/02**

Update count: **0**

Registration date

2020-12-22, 1399/10/02

Registrant information

Name

Mohammad Ali Mansouri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3629 9121

Email address

mm.9872ali@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-01-19, 1399/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of two preoperative asepsis methods with 10% Povidone Iodine alone and 10% Povidone Iodine sequences followed by 70% Ethanol on the microbial load of surgery area and bacterial identification in patients who are candidates for open heart surgery

Public title
Comparison of disinfection effect with two methods of using betadine alone and sequence of betadine and then alcohol on the number and type of microbes in the operation area

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Candidate for heart surgery
No infectious skin diseases
No allergies to antiseptics
People with diabetes
Exclusion criteria:
The patient's unwillingness to continue cooperating
Negative culture results before primary prep in both groups

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **90**
More than 1 sample in each individual
Number of samples in each individual: **5**
The frequency of microbial sampling consists of three steps: before prep, sampling will be performed from the operation area and also from the patients' noses to determine the carriers of Staphylococcus aureus. After prep, sampling from the operation area will be done in both groups and to compare the durability of the disinfectant solution at the end of the operation, sampling will be done again in both groups from the wound depth of the operation area.

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is designed so that patients have no knowledge of the type of substance used to disinfect the operating area, and physicians have no knowledge of what group each patient falls into.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Sadoughi University of Medical Sciences, Yazd

Street address

Imam Jafar Sadegh Boulevard towards Mahdiah Square, Mahdiah 2 dead end, Teachers Complex
Imam Jafar Sadegh Boulevard towards Mahdiah Square

City

Yazd

Province

Yazd

Postal code

8916795597

Approval date

2020-05-09, 1399/02/20

Ethics committee reference number

IR.SSU.SPH.REC.1399.037

Health conditions studied

1

Description of health condition studied

Microbial load and mass of the operating area

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Microbial load and mass of the operating area

Timepoint

Before disinfection of the operation area, after disinfection of the operation area, at the end of the operation

Method of measurement

Use of mannitol salt agar, blood agar, eosin methylene blue agar media and differential media

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, 10% betadine sequence and then 70 ° ethanol or 70% alcohol are used to disinfect the operation area.

Category

Prevention

2**Description**

Control group: In this group, 10% betadine alone is used to disinfect the operating area.

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Afshar Hospital

Full name of responsible person

Mohammad Ali Mansouri

Street address

Jomhory Boulevard, Afshar Hospital

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

Mohammad Ali Mansouri

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Bahonar Square, the central building of Shahid Sadoughi University of Medical Sciences, Yazd

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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

Yazd University of Medical Sciences

Proportion provided by this source

50

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

Maryam Sadeh

Position

Consultant

Latest degree

Ph.D.

Other areas of specialty/work

bacteriology

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Imam Hossein Square, at the beginning of Daneshjoo Boulevard, after the Governor's Office, Imam Reza Educational and Research Complex, School of Paramedical Sciences

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Maryam Sadeh

Position

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Person responsible for updating data**Contact****Name of organization / entity**

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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

Yes - There is 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

All data will potentially be shared after identifying individuals.

When the data will become available and for how long

6 months after printing the results

To whom data/document is available

Researchers working in academic and scientific institutes of medical sciences

Under which criteria data/document could be used

All researchers working in academic and scientific institutes of medical sciences in the country can access the published results of the study.

From where data/document is obtainable

Dr. Maryam Sadeh, sadeh_m20@yahoo.com

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

The applicant can submit his/her application via email to be reviewed.

Comments