Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Efficacy of Silver based antiseptics application for control of Central Venous catheters colonization in cardiac surgery

Protocol summary

Summary

Central venous (CV) catheters play an essential role in the management of critically ill patients in the Intensive Care Unit (ICU).CV lines are, however, allied to catheter-associated blood stream infections.Bacterial colonization of CV lines is deemed the main cause of catheter-associated infection. The purpose of our study is to compare bacterial colony counts in the catheter site before CV line insertion in two groups of post-cardiac surgery patients: a group receiving Sanosil (an antiseptic agent composed of H2O2 and silver) and a control group. The study is design as an interventional prospective double-blinded clinical trial recruited the patients in three post-cardiac surgery ICU's of a heart center. 250 patients will be randomized to be treated with sanosil plus their rutine infection control prophyilactic mrasures or without it. The participants will divided into interventional and control groups. Sanosil spray will be added to the routine preparation procedure (Chlorhexidine bath one day before and scrub with Povidone-Iodine just before the CV line insertion). After the removal of the CV lines atanaverage of three days, the catheters tips will be sent for culture and evaluation of colony counts.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201009014672N1**
Registration date: **2013-05-25, 1392/03/04**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-05-25, 1392/03/04

Registrant information

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Fardin Yousefshahi
Name of organization / entity
Tehran University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2013-03-21, 1392/01/01

Expected recruitment end date

2013-05-22, 1392/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Silver based antiseptics application for control of Central Venous catheters colonization in cardiac surgery

Public title

Efficacy of Silver based antiseptics application for decrease of Central Venous catheter infections

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: candidate for open-heart surgery in Tehran Heart Center; signing the consent for participation in the study; without any evidence of

infection at the time of admission. Exclusion criteria: infection on arrival or occurrence of infection in first 48 hours after arrival; not being admitted to the post ICU for any reason.

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **250**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tehran University of Medical Sciences

Street address
PO Box 1417614411, Floor 8, Tehran University of Medical Sciences, Qods Street, Tehran, Iran.

City
Tehran

Postal code

Approval date
2010-12-12, 1389/09/21

Ethics committee reference number
130/1122/89/د

Health conditions studied

1

Description of health condition studied
catheter related infection profilaxis

ICD-10 code
B99

ICD-10 code description
Other and unspecified infectious diseases

Primary outcomes

1

Description
colonization of bacteria in Central Venous Catheter

Timepoint
after catheter removal

Method of measurement
positive or negative cultures

2

Description
the type of isolated microorganism from the CVline

Timepoint
after catheter removal

Method of measurement
the type of microorganism

Secondary outcomes

1

Description
leuckocytosis

Timepoint
admission period

Method of measurement
wight blood cell count more than normal value

2

Description
Ferver

Timepoint
admission period

Method of measurement
body temperature more than 37.8 centigrade

3

Description
sepsis symptoms and signs

Timepoint
admission period

Method of measurement
evaluation of clinical and para-clinical factores

Intervention groups

1

Description
Sanosil spraying on the insertion point by an standard spray, 3 puffs, half an hour before surgery, in preparation room

Category
Treatment - Drugs

2

Description
distilled water spraying on the insertion point by an standard spray, 3 puffs, half an hour before surgery, in preparation room
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran Heart Center
Full name of responsible person
Fardin Yousefshahi
Street address
Tehran Heart Center, Al-ahmad & Kargar Cross
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran Heart Center, Infection Control Section
Full name of responsible person
Dr. Mohamadali Broomand
Street address
Infection Control section, Tehran Heart Center, Al-ahmad & Kargar Cross, Tehran, Iran.
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran Heart Center, Infection Control Section
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
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Person responsible for updating data

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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