# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

20 Jun 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**

**Name**
Fardin Yousefshahi
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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
**City**
Tehran

## 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**
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## Person responsible for scientific inquiries

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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*