

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of effect of povidone iodine 7.5% versus sequential povidone iodine and decosept hand scrub on incidence of local symptoms of infection at the site of cardiac implantable electronic device

Protocol summary

Summary

This clinical trial comparison of effect of povidone iodine 7.5% versus sequential povidone iodine and decosept hand scrub on incidence of local symptom of infection at the site of cardiac implantable electronic device. 220 patient randomised divided two groups Type of trial: Random sampling block the way of information search: questionnaire and checklist Inclusion criteria: "no given immunosuppressive drug" - "no given antibiotic" - "no problem in immunosystem" - "no problem extremity" - "candidated" Exclusion criteria: "lack of patient satisfaction" - "fever -INR>2" patient randomised divided in two groups: Interventional group 1: after general cleansing hand scrub with betadine 7.5% for 3 minutes, using 5 ml of decosept then were dried with sterile towels Control group: after general cleansing hand scrub with betadine 7.5% for 3 minutes, using then were dried with sterile towels. In presence local symptom of infection at the site of cardiac implantable electronic device after 24 hours and then 3 months were reported.

General information

Acronym

CIED

IRCT registration information

IRCT registration number: **IRCT2015051822301N1**

Registration date: **2016-03-02, 1394/12/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-03-02, 1394/12/12

Registrant information

Name

Khadige Rashedimanesh

Name of organization / entity

Shiraz university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 3832 0746

Email address

stud2295296137@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

government

Expected recruitment start date

2015-02-20, 1393/12/01

Expected recruitment end date

2015-05-22, 1394/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effect of povidone iodine 7.5% versus sequential povidone iodine and decosept hand scrub on incidence of local symptoms of infection at the site of cardiac implantable electronic device

Public title

effect of povidone iodine 7.5% sequential decosept hand scrub on decrease of incidence of local symptoms of infection at the site of cardiac implantable device electronic device

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: "no given immunosuppressive drug" - "no given antibiotic" - "no problem in immune system" - "no problem extrinsically" - "candidiasis" Exclusion criteria: "lack of patient satisfaction" - "fever -INR>2"

Age

From **3 days** old to **93 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **220**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

incidence of cied

Secondary Ids

1

Registry name

-

Secondary trial Id

-

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Zand street Shiraz University of Medical Sciences

City

Shiraz

Postal code

71345-1978

Approval date

2015-04-07, 1394/01/18

Ethics committee reference number

IR.SUMS.REC.CT-93-7433

Health conditions studied

1

Description of health condition studied

Heart failure

ICD-10 code

I50.1

ICD-10 code description

نارسایی قلبی

Primary outcomes

1

Description

Incidence of infection

Timepoint

24 hours and at least 3 months after intervention

Method of measurement

Checklist and clinical presentation

Secondary outcomes

1

Description

Erythema -swelling -hematoma-fever-drainage

Timepoint

1 day and 3 months after intervention

Method of measurement

Checklist and presentation

Intervention groups

1

Description

Intervention Group: 110 patients that surgical team hand scrub with povidone iodine 7.5 percent then to dried with sterile towel then sequentially used decosept gel.

Category

Prevention

2

Description

control: routine scrub 110 patients that surgical team hand scrub with povidone iodine 7.5 percent only

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Faghihi Hospital

Full name of responsible person

Dr. Nikoo

Street address

Zand street Faghihi hospital angiography ward

City

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for reasearch, Shiraz University of Medical Sciences

Full name of responsible person

Dr poostfroosh

Street address

Zand stree, Shiraz University of Medical Science

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for reasearch, Shiraz University of Medical Sciences

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

Shiraz University of Nursing of Sciences

Full name of responsible person

Zahra molazem

Position

Phd nursing

Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

Rashdیمانesh khadijeh

Position

Master

Other areas of specialty/work

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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