Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparing the Effect of preoperative skin preparation with povidone-iodine and chlorhexidine-gluconate on the surgical site infection

Protocol summary

Study aim

The purpose of this study was to determine and compare the effect of skin preparation with povidone iodine and chlorhexidine gluconate on surgical site infection rate in laparotomy patients.

Design

clinical trial with control group, 70 participants, randomized by the time of admission, parallel groups.

Settings and conduct

Research environment were the selected Educational and medical centers of Iran university of medical science. After collection of preliminary data and getting consent, patients were transferred to operating room. they were put under general anesthesia and then skin preparation of surgical site was done by the researcher with standard rotational method in two steps for each group. Patients were blinded by not telling them about which group they were going to be divided in. Data analyzer was blinded by Assigning specific numbers to patients.

Participants/Inclusion and exclusion criteria

Inclusion criteria consists of age between 18 to 55 years, minimum diploma degree, signing the consent form, no history of abdominal surgery. Exclusion criteria consists of the following: diabetes, body mass index more than 35, presence of immunodeficiency, administration of immunosuppressive drugs, presence of local infection near the surgical site or systemic infection, allergic reaction to antiseptics used in this study, history of malignancy, presence of severe skin rash near the surgical site, history of radiotherapy, administration of broad spectrum antibiotics less than 30 days before surgery, emergency surgery, any incidents that may contaminate the surgical field or surgical instruments.

Intervention groups

skin preparation of surgical site in the control group was done with povidone iodine antiseptic. skin preparation of surgical site in the intervention group was done with chlorhexidine gluconate antiseptic.

Main outcome variables

Surgical site infection rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220206053955N1**
Registration date: **2022-03-15, 1400/12/24**
Registration timing: **retrospective**

Last update: **2022-03-15, 1400/12/24**
Update count: **0**

Registration date

2022-03-15, 1400/12/24

Registrant information

Name

Arash Khajehvand

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 28 3377 4148

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-21, 1400/02/01

Expected recruitment end date

2021-09-22, 1400/06/31

Actual recruitment start date

2021-04-21, 1400/02/01

Actual recruitment end date

2021-09-22, 1400/06/31

Trial completion date

2021-09-22, 1400/06/31

Scientific title
Comparing the Effect of preoperative skin preparation with povidone-iodine and chlorhexidine-gluconate on the surgical site infection

Public title
Comparing the Effect of preoperative skin preparation with povidone-iodine and chlorhexidine-gluconate on the surgical site infection

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
participants age between 18 to 55 years old participants at least have a high school diploma no past history of abdominal surgery sign the consent form of this study

Exclusion criteria:
presence of diabetes mellitus Body mass index more than 35 presence of immunodeficiency administration of immunosuppressive drugs presence of local infection near the surgical site or systemic infection Allergic reaction to any of antiseptic agents history of Malignancy presence of Skin rash near the surgical site history of radiotherapy administration of broad spectrum antibiotics less than one month before surgery emergency surgery any disruption in surgical theater that may leads to contamination of surgical instruments or surgical field during the surgery

Age
From **18 years** old to **55 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **70**
Actual sample size reached: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization was done with random number table made by computer. According to the random number table, each patient was given a specific number which only the researcher was aware of it.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants and data analyzers were blinded to which antiseptic we used in study. however, surgeon and surgical team as well as the researcher knew about which antiseptics were used for patients because of their color.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Iran university of medical sciences

Street address
Hemmat Highway, next to Milad Tower, Iran University of Medical Sciences

City
Tehran

Province
Tehran

Postal code
1449614535

Approval date
2021-03-17, 1399/12/27

Ethics committee reference number
IR.IUMS.REC.1400.013

Health conditions studied

1

Description of health condition studied
Surgical site infection, Antiseptic, Povidone Iodine, Chlorhexidine Gluconate, Skin Preparation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Surgical site infection

Timepoint
Surgical site infection rate in period of 30 days after surgery were compared in both groups.

Method of measurement
Data collection tools were demographic data forms and surgical site infection assessment forms

Secondary outcomes

empty

Intervention groups

1

Description
Control group: After the induction of general anesthesia, the first step of surgical site skin preparation (skin prep)

was done with povidone iodine 7.5% solution for about 3-5 minutes by the researcher with standard rotational method. then the remains of antiseptic solution was cleaned with sterile towel. The second step of skin prep was done with povidone iodine 10% solution and the procedure was like the first step.

Category

Prevention

2

Description

Intervention group: After the induction of general anesthesia, the first step of surgical site skin preparation (skin prep) was done with chlorhexidine gluconate 2% / isopropyl alcohol 70% solution for about 3-5 minutes by the researcher with standard rotational method. then the remains of antiseptic solution was cleaned with sterile towel. The second step of skin prep was done with chlorhexidine gluconate 2% / isopropyl alcohol 70% solution and the procedure was like the first step.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar hospital

Full name of responsible person

Arash khajehvand

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Fardin Amiri

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Grant name

Grant code / Reference number

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

No

Title of funding source

Iran University of Medical Sciences

Proportion provided by this source

1

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Arash Khajehvand

Position

M.Sc. student

Latest degree

Master

Other areas of specialty/work

Surgical Technology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable