

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Survey and comparison the effect of skin preparation with povidone-iodine, chlorhexidine and alcohol antiseptics on microbial counts of surgical site in abdominal surgery patients referring to selected hospitals of Iran University of Medical Sciences

Protocol summary

Study aim

Survey and comparison the effect of skin preparation with povidone-iodine, chlorhexidine and alcohol antiseptics on microbial counts of surgical site in abdominal surgery patients referring to selected hospitals of Iran University of Medical Sciences

Design

Three parallel groups with 40 patient in each group, double blind and randomized by lottery with proportional allocation

Settings and conduct

This study is a clinical trial study performed on abdominal surgery patients referred to selected hospitals of Iran University of Medical Sciences (Hazrat Rasoul and Firoozgar). The sample consisted of 120 patients with abdominal surgery who were randomly divided into three groups of 40 patients (3 subjects in each group and 360 subjects in total). For blinding, each sample was assigned a code and only the researcher knew that patient where in which group and the rest of the research team were not aware of this.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients undergoing elective abdominal surgery were at least 18 years of age. Exclusion criteria: Patients with a history of the following diseases: Inflammatory skin diseases - A history of allergies to alcohol, povidone iodine and chlorhexidine - Wounds or any visible skin lesions in the abdominal area - Prohibition on the use of disinfectants for perforation - Immune deficiency - Patients who use immunosuppressants.

Intervention groups

patients with elective abdominal surgery divided into three groups: Group 1: Skin preparation with Povidone iodine 7/5% and Povidone iodine 10%; Group 2: Skin preparation with povidone iodine 7/5%, alcohol 70% and

povidone iodine 10%; Group 3: Skin preparation with chlorhexidine in alcohol and povidone iodine 10%

Main outcome variables

Microbial counts of surgical site

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190821044575N1**

Registration date: **2019-11-07, 1398/08/16**

Registration timing: **retrospective**

Last update: **2019-11-07, 1398/08/16**

Update count: **0**

Registration date

2019-11-07, 1398/08/16

Registrant information

Name

Hamed Taghiloo

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3354 7131

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-14, 1397/11/25

Expected recruitment end date

2019-07-06, 1398/04/15
Actual recruitment start date
2019-03-16, 1397/12/25
Actual recruitment end date
2019-07-21, 1398/04/30
Trial completion date
2019-07-21, 1398/04/30

Scientific title

Survey and comparison the effect of skin preparation with povidone-iodine, chlorhexidine and alcohol antiseptics on microbial counts of surgical site in abdominal surgery patients referring to selected hospitals of Iran University of Medical Sciences

Public title

Evaluation and comparison of Povidone iodine, Chlorhexidine and alcohol on microbial count

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients undergoing elective abdominal surgery Being at least 18 years old

Exclusion criteria:

Inflammatory skin diseases Having a history of alcohol , povidone iodine and chlorhexidine allergies Wounds or any visible skin lesions in the abdominal area Prohibition on the use of disinfectants for skin prep Patients with Immune Deficiency Patients taking immunosuppressive drugs.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **120**

Actual sample size reached: **120**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

For blinding, each of the samples taken from the patients was coded for blindness, and only the researcher knew in which group the individual was located and the rest of the research team was unaware of this.

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

Iran University of Medical Sciences,Next to Milad Tower; Hemmat Highway,Tehran

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2019-02-14, 1397/11/25

Ethics committee reference number

IR.IUMS.REC.1397.1125

Health conditions studied

1

Description of health condition studied

Selective abdominal surgery patients

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Microbial count rate

Timepoint

Cultures were taken before skin preparation, after primary skin preparation and after secondary skin preparation.

Method of measurement

Data collection tools included demographic data form and number and type of colonies of microorganisms

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group 1: Before the intervention, a microbial culture was harvested from the skin of the surgical site then Primary skin preparation with povidone-iodine 7.5% antiseptic was carried out for 5 minutes. After antiseptic

drying, microbial culture was harvested. Secondary skin preparation was performed with povidone-iodine 10% antiseptic for 2 minutes and after drying this antiseptic the third culture sample was taken.

Category

Prevention

2**Description**

Intervention Group 2: Before the intervention, a microbial culture was harvested from the skin of surgical site then Primary skin preparation with povidone-iodine 7.5% antiseptic was carried out for five minutes and then After drying it skin prep with alcohol performed for one minute and after antiseptic drying, microbial culture was harvested. Secondary skin preparation was performed with povidone-iodine 10% antiseptic for two minutes and after drying this antiseptic the third culture sample was taken.

Category

Prevention

3**Description**

Intervention Group 3: Before the intervention, a microbial culture was harvested from the skin of the surgical site then Primary skin preparation with chlorhexidine 2% in alcohol 70% antiseptic was carried out for two minutes then after antiseptic drying, microbial culture was harvested. Secondary skin preparation was performed with povidone-iodine 10% antiseptic for two minutes and after drying this antiseptic the third culture sample was taken

Category

Prevention

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

Hazrat Rasoul Akram hospital and Firouzgar hospital

Full name of responsible person

Hamed Taghiloo

Street address

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

Iran University of Medical Sciences

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?**

Yes

Title of funding source

Iran University of Medical Sciences

Proportion provided by this source

100

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**

Iran University of Medical Sciences

Full name of responsible person

Hamed Taghiloo

Position

Masters student

Latest degree

Master

Other areas of specialty/work

surgical technologist

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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