# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 2026

## Comparison of the effect of surgical site skin preparation with povidone-iodine antiseptic at two different temperatures on the microbial load and surgical site infection in laparotomy patients

### Protocol summary

**Study aim**
Comparison of the effect of surgical site skin preparation with povidone iodine at two different temperatures

**Design**
clinical trial with control and intervention groups, with parallel groups, single-blinded, randomized and phase 3 on 126 patients. the table of random numbers made by the computer will be used for study randomization.

**Settings and conduct**
This study will be conducted in the operating room by taking microbial cultures from the surgical site skin in three stages; before surgical site skin preparation, after the primary stage and after the secondary stage of surgical site skin preparation. the incidence of surgical site infection in 24 hours and 30 days after the operation will be checked. In this study, the participants will not be informed about the temperature of the antiseptic solution used.

**Participants/Inclusion and exclusion criteria**
Absence of immune system deficiency and malignancy Not being allergic to povidone-iodine antiseptic Age 18 to 55 years Elective surgery No contamination of instruments or surgical field

**Intervention groups**
In the intervention group, the secondary stage of surgical site skin preparation will be performed with 10% povidone-iodine at a temperature of 35°C and in the control group at a temperature of 22°C .

**Main outcome variables**
povidone-iodine antiseptic at two different temperatures; microbial load; surgical site infection

### General information

**Reason for update**
**Acronym**
**IRCT registration information**
IRCT registration number: **IRCT20240212060966N1**
Registration date: **2024-02-21, 1402/12/02**
Registration timing: **prospective**

Last update: **2024-02-21, 1402/12/02**
Update count: **0**

**Registration date**
2024-02-21, 1402/12/02

**Registrant information**
**Name**
Diba Nikkhah dashtizadeh
**Name of organization / entity**
**Country**
Iran (Islamic Republic of)
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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2024-04-13, 1403/01/25
**Expected recruitment end date**
2024-09-15, 1403/06/25
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Comparison of the effect of surgical site skin preparation with povidone-iodine antiseptic at two different temperatures on the microbial load and surgical site

infection in laparotomy patients

**Public title**
Comparison of the effect of surgical site skin preparation with povidone-iodine solution at two different temperatures on the antimicrobial effect and surgical wound infection

**Purpose**
Prevention

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Age 18 to 55 years Having at least a diploma degree No diabetes No history of laparotomy surgery Body mass index less than 35 Absence of immune system deficiency and no use of immunosuppressive drugs Absence of local infection near the surgical site or systemic infection Not being allergic to povidone-iodine antiseptic No history of malignancy and radiation therapy Absence of severe skin rash at the surgical site Not using broad-spectrum antibiotics within a month before going to the hospital having Elective surgery

**Exclusion criteria:**
Emergency laparotomy surgery Disruption in the surgical process that leads to the contamination of the instruments or the surgical field immune system deficiency and using immunosuppressive drugs having diabetes allergic to povidone-iodine antiseptic The presence of rashes and severe skin diseases at the surgical site using broad-spectrum antibiotics within a month before going to the hospital morbid obesity

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

**Gender**
Both

**Phase**
3

**Groups that have been masked**

- Participant

**Sample size**
Target sample size: **126**
More than 1 sample in each individual
Number of samples in each individual: **3**
Microbial cultures will be taken from the skin of the abdomen at the surgical site in three stages before surgical skin preparation, after primary surgical skin preparation and after secondary surgical skin preparation.

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
Randomization method: simple randomization
Randomization tool: using a table of random numbers made by the computer

**Blinding (investigator's opinion)**
Single blinded

**Blinding description**
In this research, single blinding will be used; So that the samples will not be informed about the antiseptic temperature used for them. But the researcher and the surgical team will know the antiseptic temperature used for each sample.

**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**
Faculty of allied medicine, Iran univarsity of medical sciences ,Hemmat highway, next to the milad tower, tehran, iran

**City**
Tehran

**Province**
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1449614535

**Approval date**
2024-02-05, 1402/11/16

**Ethics committee reference number**
IR.IUMS.REC.1402.1008

## Health conditions studied

### 1

**Description of health condition studied**
Surgical site infection

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

### 1

**Description**
Microbial load

**Timepoint**
microbial cultures will be taken in three stages before the surgical site skin preparation, after the initial stage of disinfection of the surgical site and after the secondary stage of disinfection of the surgical site with povidone-iodine 10%.

**Method of measurement**
taking microbial culture and counting microbial colonies 24 hours after incubation

### 2

**Description**
Surgical site infection

**Timepoint**
Observation and examination of the surgical wound after 24 hours and 30 days after surgery
**Method of measurement**
Observing and examining the surgical wound and entering the symptoms in the surgical site infection checklist

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: surgical site Skin preparation will be done in two stages. At first, before starting the skin preparation process, a culture will be taken from the skin of the surgical site with a sterile swab. In this way, an initial culture sample will be taken using a wet swab soaked in physiological serum and the swab will be rubbed on the blood agar culture medium. Then, in the initial stage of skin preparation, povidone-iodine 7.5% will be used at a temperature of 22 degrees Celsius. The skin preparation will be done in a circular manner from the center of the surgical incision to the periphery and this will be done with 3 separate sterile gauzes. After performing the initial stage of skin preparation,we will wait for 5 minutes and then the antiseptic residue will be dried by a sterile cloth. Before starting the secondary stage, a skin culture will be taken from the surgical site. The second culture sample will be taken using a sterile swab dipped in physiological serum. In this way, the swab will be rubbed on the blood agar medium. Then, in the secondary stage, povidone-iodine 10% will be used at a temperature of 35 degrees Celsius. Skin preparation will be done in a circular manner from the center of the surgical incision to the periphery by 3 separate gas sterilizers. After performing the secondary stage of skin preparation, we will wait for 5 minutes and then the antiseptic residue will be dried by a sterile cloth. Again, a culture will be taken from the skin of the surgical site with a sterile swab dipped in physiological serum. In this way, the swab will be rubbed on the blood agar culture medium. Then, the surgical site will be covered with sterile cloths and sterile plastic covers, and the surgical process will continue. The culture samples will be sent to the laboratory to determine the microbial load. 24 hours after the surgery, the dressing of the surgical site will be changed for the first time by the researcher and the relevant doctor. The surgical site will be observed and examined for signs of surgical site infection. The symptoms will be recorded in the researcher's form for recording surgical site infection symptoms. The patient will be trained. The form for recording the symptoms of surgical site infection will be provided to the patient so that he or she can check the surgical site within one month after the surgery and record the symptoms in the said form. Then at the end of 30 days of the said form will be collected by the researcher. Finally, two groups will be compared.
**Category**
Prevention

### 2

**Description**
Control group: Surgical site skin preparation will be done in two stages. First, before starting the skin preparation process, a sterile swab will be taken from the skin of the surgical site. In this way, a primary culture sample will be taken using a wet swab dipped in physiological serum and rubbed on the blood agar culture medium. Then, in the initial stage of skin preparation, povidone iodine 7.5% will be used at a temperature of 22 degrees Celsius. Skin preparation will be done in a circular manner from the center of the surgical incision to the periphery, and this will be done with 3 separate sterile gauzes. After performing the initial stage of skin preparation, we will wait for 5 minutes and then the antiseptic residue will be dried by a sterile cloth. Before starting the secondary stage, the second culture will be taken from the skin of the surgical site. Then, in the secondary stage, povidone-iodine 10% at 22°C will be used. The preparation of the skin will be done in a circular manner from the center of the surgical incision to the periphery by 3 separate gas sterilizers. After performing the secondary stage of skin preparation, we will wait for 5 minutes and then the antiseptic residue will be dried by a sterile cloth. Again, a culture will be taken from the skin of the surgical site with a sterile swab dipped in physiological serum. Then, the surgical site will be covered with sterile cloths and sterile plastic covers, and the surgical process will continue. Culture samples will be sent to the laboratory to determine the microbial load. 24 hours after the surgery, the dressing of the surgical site will be changed for the first time by the researcher and the relevant doctor. The surgical site will be observed and examined for signs of surgical site infection. The symptoms will be recorded in the researcher's form for recording surgical site infection symptoms. The patient will be trained. The form for recording the symptoms of surgical site infection will be provided to the patient so that he or she can check the surgical site within one month after the surgery and record the symptoms in the said form. Then at the end of 30 days of the said form will be collected by the researcher. Finally, two groups will be compared.
**Category**
Prevention

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Firouzgar Medical Education Center
**Full name of responsible person**
Fardin amiri
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Firouzgar Hospital, Beh Afrin St., Waliasr Square,

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**2**

**Recruitment center**

**Name of recruitment center**
Rasul Akram Medical Research Teaching Center

**Full name of responsible person**
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## Sponsors / Funding sources

**1**

**Sponsor**

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Dr. Reza Falak

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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**
Fardin Amiri

**Position**
Assistant Professor, Faculty member of the operating room group

**Latest degree**
Ph.D.

**Other areas of specialty/work**
Medical Education

**Street address**
Faculty of Paramedicine,Iran University of Medical Sciences, between the intersection of Sheikh Fazlullah Nouri and Shahid Chamran, Shahid Hammat highway, next to milad tower, Tehran, Iran

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## Person responsible for scientific inquiries

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**Position**
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**Latest degree**
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**Other areas of specialty/work**
Medical Education

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**
There is no further information

**Study Protocol**
Yes - There is 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**
Yes - There is a plan to make this available

**Analytic Code**
Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**
Undecided - It is not yet known if there will be a plan to make this available

**Title and more details about the data/document**
Only part of the data will be shared, such as information on the main outcomes.

**When the data will become available and for how long**
The access period starts after the results are printed

**To whom data/document is available**
Students, employees and researchers working in academic and clinical institutions and medical sciences

**Under which criteria data/document could be used**
Researchers working in academic institutions of medical sciences

**From where data/document is obtainable**
To access the data, refer to the person in charge of updating the project information. Name and surname: Diba Nikkhah Dashtizadeh Email address: nikkhahdiba@gmail.com Contact number: 09163531396

**What processes are involved for a request to access data/document**
In order to access the data, correspond with the person in charge of updating the information of the project via e-mail, and if the thesis project supervisor approves, the project data will be available to the applicants.

**Comments**