Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Clinical trials of surgical site with disinfectant spray Chlorhexidine-Alcohol compared to those who received Povidone-Iodine to reduce the amount of infection in surgery.

Protocol summary

Summary

Objectives: Due to limited studies in this regard, especially the cultivation of the surgical site after surgery has been done. We decide to check and compare disinfect the skin with Povidone-Iodine and Chlorhexidine-Alcohol surgery in patients undergoing non-emergency surgery in the Baqiyatallah hospital too. Design: This is a triple-blind, randomized clinical trial. Setting and conduct: This study will perform at the Baqiyatallah University of Medical Sciences. In this study, the patients, measuring the outcomes of study participants (researchers) or Data Monitoring Committee (analyzers) of the patients unaware about intervention. Hospital patients undergoing elective abdominal surgery (clean-contaminated) were put into the project. Clean-contaminated surgery, including elective cholecystectomy and operation of the digestive system that includes a variety of Gastrostomy, resection of the small intestine, are the colectomy. Patients in both groups will divide randomly using a table of random numbers. Count of Bacteria is another outcome in this study and assess using the laboratory. This clinical trial is a phase 2 study. Major Inclusion and Exclusion criteria: All patients who do not follow. Patients who will died during this study. Clear immunocompromised patients (transplant patients and AIDS), chronic skin disease, radiation therapy and chronic inflammatory disease. Intervention: 100 patients with Povidone-Iodine and 100 people using Chlorhexidine antiseptic alcohol will evaluate. Main outcome measures (variables): The main outcome of this study is the infection and numbers of Bacteria.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015110724706N1**
Registration date: **2016-05-02, 1395/02/13**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-05-02, 1395/02/13

Registrant information

Name

Reza Mirnejad

Name of organization / entity

Baqiyatallah university of medical sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Baqiyatallah University of Medical Sciences

Expected recruitment start date

2015-04-21, 1394/02/01

Expected recruitment end date

2016-03-20, 1395/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trials of surgical site with disinfectant spray Chlorhexidine-Alcohol compared to those who received Povidone-Iodine to reduce the amount of infection in surgery.

Public title
Comparison of the results and complication of the two methods Chlorhexidine–Alcohol and Povidone–Iodine in non-emergency abdominal surgery
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: Hospital patients undergoing elective abdominal surgery (clean-contaminated) were put into the project. Exclusion criteria: All patients who do not follow. Patients who died during this study; Clear immunocompromised patients (transplant patients and AIDS), chronic skin disease; radiation therapy and chronic inflammatory disease; All patients who do not follow; Patients who died during this study.
Age
From **20 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **200**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Triple blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Baqiyatallah University of Medical Sciences
Street address
Postal code: 1435917541, Mollasadra, St - Sheikh Bahaee, St, Tehran
City
Tehran
Postal code
1435917541
Approval date
2014-09-23, 1393/07/01
Ethics committee reference number
ir.bmsu.rec.94.51

Health conditions studied

1

Description of health condition studied
Infection abdominal postoperative
ICD-10 code
T81.5
ICD-10 code description
Foreign body accidentally left in body cavity or operation wound following a procedure

Primary outcomes

1

Description
Infection
Timepoint
One and two weeks after operation
Method of measurement
Medical evaluation

Secondary outcomes

1

Description
The number of bacteria grown
Timepoint
One and two weeks after operation
Method of measurement
Laboratory

Intervention groups

1

Description
Intervention 2: Povidone–Iodine (Betadin), 10 milliliters once before surgery, Povidone–Iodine is a stable chemical complex of Polyvinylpyrrolidone (Povidone, PVP) and elemental iodine. It contains from 9.0% to 12.0% available iodine, calculated on a dry basis. Brand of Penthrox is Methoxyflurane. Brand of Povidone–Iodine is Betadin. Povidone-iodine applied to an abrasion using a cotton swab.
Category
Prevention

2

Description
Intervention 1: Spray disinfectant Chlorhexidine-alcohol, 10 milliliters once before surgery, Chlorhexidine-Alcohol based chlorhexidine Gluconate and 70% isopropyl alcohol 2% D is formulated. How to use: Chlorhexidine-

alcohol solutions in areas of the skin spray and wait for 30 minutes to dry. Brand of Chlorhexidine-Alcohol is Badi Prop.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Surgery Department of Baqiyatallah hospital

Full name of responsible person

Moharam Mohammadian

Street address

Postal code: 1435917541, Mollasadra Street, Sheikh Bahaee St, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Baqiyatallah University of Medical Sciences

Full name of responsible person

Hamid Reza Rasouli

Street address

Postal code: 1435917541, Mollasadra Street, Sheikh Bahaee Street, Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Baqiyatallah 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

Baqiyatallah University of Medical Sciences

Full name of responsible person

Ali Ebrahimi

Position

Faculty member, Plastic surgery

Other areas of specialty/work

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Person responsible for scientific inquiries

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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