

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 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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Iran (Islamic Republic of)

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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 Pentrox 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

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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

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

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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

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