Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

A randomized clinical trial of chlorhexzidine alcohol 4% compared with povidin Iodine 10% for vaginal scrub in gynecologic surgeries: complications and microbial flora

Protocol summary

Study aim
Comparison of the effects of 4% alcohol chlorhexidine and 10% iodine for vaginal lavage in gynecological surgeries: Complications and microbial flora

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 per 100 patients using random number table

Settings and conduct
Study will be done in Al zahra hospital of Tabriz. Sampling is done using convenience sampling method and the number of statistical samples of the study are 108 people who are equally divided into two control and experimental groups. first, using a table of random numbers, a sequence of letters of the web will be produced equal to the number of statistical samples and equally for the two experimental and control groups. Anti-septic solutions are marked with two English letters A&B and according to the sequence of letters created, they will be used in a double-blind manner depending on the type of intervention in the case and control groups, and the solution symbol used in the data collection sheet will be recorded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: candidates for elective vaginal surgery؛ Satisfaction to participate in the study؛ All patients aged 18 to 65 years with indication for vaginal surgery. Exclusion criteria: Sensitivity to povidone iodine or chlorhexidine alcohol؛ Evidence of active infection at the site of surgery؛ Having systemic diseases predisposing to infections such as diabetes and immunodeficiency disease؛ Taking cytotoxic drugs and corticosteroids in the last 6 months؛ Existence of active wound or laceration at the operation site؛ BMI above 30؛ Patient discharge on the day of surgery.

Intervention groups
Comparison of the effects of chlorhexidine alcohol and Ipovidine iodine on vaginal lavage in gynecological vaginal surgeries

Main outcome variables
Strength, durability, side effects of chlorhexidine alcohol and Ipovidine iodine

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200919048755N1**
Registration date: **2020-11-19, 1399/08/29**
Registration timing: **retrospective**

Last update: **2020-11-19, 1399/08/29**
Update count: **0**

Registration date
2020-11-19, 1399/08/29

Registrant information

Name
Hamed Fallah

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 41 3668 0583

Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-02-19, 1398/11/30

Expected recruitment end date
2020-10-21, 1399/07/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A randomized clinical trial of chlorhexzidine alcohol 4% compared with povidin Iodine 10% for vaginal scrub in gynecologic surgeries: complications and microbial flora

Public title
A randomized clinical trial of chlorhexzidine alcohol 4% compared with povidin Iodine 10% for vaginal scrub in gynecologic surgeries: complications and microbial flora
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients referred to Al-Zahra Hospital in Tabriz and candidates for elective vaginal surgery Consent to participate in the study
Exclusion criteria:
Hypersensitivity to povidine iodine or chlorhexidine alcohol Evidence of active infection at the site of surgery Having systemic diseases predisposing to infections such as diabetes or immunodeficiency diseases such as HIV Taking cytotoxic drugs and corticosteroids in the last 6 months Existence of active wound or laceration at the operation site BmI>30 Discharge of the patient on the day of surgery
Age
From **18 years** old to **65 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
The sampling method will be as follows: first, using a table of random numbers, a sequence of letters A and B. The same number of statistical samples will be produced equally for the two experimental and control groups. Anti-diaphonic solutions are marked with two English letters A and B and according to the sequence of letters created, they will be used in two ways depending on the type of intervention (solution) in both case and control groups and the solution symbol used on the data sheet collection will be recorded.
Blinding (investigator's opinion)
Double blinded
Blinding description
The sampling method will be as follows: first, using a table of random numbers, a sequence of numbers;The same number of statistical samples will be produced equally for the two experimental and control groups. Anti-septic solutions are marked with two English letters A and B and according to the sequence of letters created, they will be used in two ways depending on the type of intervention (solution) in both case and control groups and the solution symbol used on the sheet. Data collection will be recorded.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committe of Tabriz University of Medical Sciences
Street address
Number29,6th dahmetri,mollasadra Blvd,Daneshgah Alley,Tabriz city
City
Tabriz
Province
East Azarbaijan
Postal code
5165943333
Approval date
2020-02-17, 1398/11/28
Ethics committee reference number
IR.TBZMED.REC.1398.1229

Health conditions studied

1

Description of health condition studied
Infection of the vaginal Scrub site in gynecological surgeries
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
povidine iodine disinfectant power
Timepoint
Before and immediately after the scrub (in the first minute)
Method of measurement
The method will be that in both groups of patients, before scrub and immediately after it (in the first minute)

microbial culture using a sterile swab and transfering it to a transport environment, based on the type and count of microorganisms will be done. The extent of vaginal microbial load reduction after the use of chlorhexidine 4% and betadine 10% solution will be determined and the data will be analyzed.

2

Description

Durability of chlorhexidine alcohol effect

Timepoint

Before and immediately after the scrub (in the first minute)

Method of measurement

To compare the shelf life of the disinfectant solution or its inactivation during bleeding at the end of surgery (in the first minute after surgery), re-sampling for culture (in the first minute) using a sterile swab and transferring it to a transport medium, will be done .

3

Description

Durability of povidone iodine effect

Timepoint

Before and immediately after the scrub (in the first minute)

Method of measurement

To compare the shelf life of the disinfectant solution or its inactivation during bleeding at the end of surgery (in the first minute after surgery), re-sampling for culture (in the first minute) using a sterile swab and transferring it to a transport medium, will be done.

4

Description

Side effects of Povidine-iodine

Timepoint

Immediately after using the solution and at the end of the operation and in the morning after the operation

Method of measurement

Observation and examination of the vulva and vagina in terms of local complications occurred in the mentioned solution based on the severity of the complication (burning, erythema, swelling and inflammation, scaling, scarring, etc.) based on the design questionnaire,immediately after using The solution ,at the end of the operation and in the morning after the operation. redness and burning at the site is considered mild complication, moderate complication is in case of scaling, and severe complication is in case of ulceration.

5

Description

Side effects of chlorhexidine alcohol

Timepoint

Immediately after using the solution and at the end of the operation and in the morning after the operation

Method of measurement

Observation and examination of the vulva and vagina in terms of local complications occurred in the mentioned solution based on the severity of the complication (burning, erythema, swelling and inflammation, scaling, scarring, etc.) based on the design questionnaire,immediately after using The solution ,at the end of the operation and in the morning after the operation. redness and burning at the site is considered mild complication, moderate complication is in case of scaling, and severe complication is in case of ulceration.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Chlorhexidine alcohol will contain 4% alcohol. Due to the fact that this antiseptic solution does not exist in our country, it will be prepared and delivered by a clinical pharmacist with the mentioned percentage in the Faculty of Pharmacology of Tabriz University of Medical Sciences. In each patient in three stages, before the operation, immediately after the operation (in the first minute) and then at the end of the operation,scrub with antiseptic solution using a sterile swab will be done, sampling of the vaginal walls and fornixes is prepared and transferred to the transport environment and Will be sent for microbial culture by one of the laboratory personnel.The operation site will be examined for local complications such as burning, inflammation, redness, scaling, and ulceration:immediately after the use of antiseptic, at the end of the operation, and in the morning after the operation by a trained nurse and will be recorded in the data sheet.

Category

Treatment - Surgery

2

Description

Control group: Povidine iodine 10%.In each patient in three stages, before the operation, immediately after the operation (in the first minute) and then at the end of the operation,scrub with antiseptic solution using a sterile swab will be done, sampling of the vaginal walls and fornixes is prepared and transferred to the transport environment and Will be sent for microbial culture by one of the laboratory personnel.The operation site will be examined for local complications such as burning, inflammation, redness, scaling, and ulceration:immediately after the use of antiseptic, at the end of the operation, and in the morning after the operation by a trained nurse and will be recorded in the data sheet.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Al Zahra hospital

Full name of responsible person
Maryam Vaezi

Street address
No.29,6th Dah metri,Mollasadra Blvd,Daneshgah alley,Tabriz city

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Maryam Vaezi

Street address
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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
Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
Maryam Vaezi

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

Street address
Number29,6th Dahmetri,Mollasadra Blvd,Daneshgah Alley,Tabriz city

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Maryam Vaezi

Position
Assisstant Professor

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

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Person responsible for updating data

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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
Undecided - It is not yet known if there will be 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