

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### Comparison study of antibacterial effectiveness of Betadine-alcohol, Decosept, septicidin and Sterillium for surgical hand anticepcis on hand bacterial flora

#### Protocol summary

##### Summary

Objective: to compare antibacterial effect of 4 surgical hand antiseptics (Betadine- ethyl alcohol 70%, Decosept, Septicidin and Sterillium) on hand bacterial flora Design: before and after clinical trial. Setting: 20 healthy volunteers aged >18 years old. Inclusion criteria: healthy volunteers whose nails were short and clean, and didn't use any substances or soap with antimicrobial activity for one week before testing. Exclusion criteria: pregnant women; presence of any cuts or abrasion on hand skin; any skin disorders. Interventions and primary and secondary outcome: before treatment volunteers washed their hand with 10 ml of a soft soap for 1 minute. After rinsing and drying bacterial culture samples of both hands were taken according to EN12791. In each intervention immediately after sampling for prevalues, subjects rubbed their hand with one of 4 products under test (Betadine- ethyl alcohol 70%, Decosept, Septicidin and Sterillium ). For evaluating efficacy of any disinfecting agent, according to EN1279, has to compare with that of reference disinfectant (propan-1-ol 60%), that is applied for 3 min; therefore volunteers rubbed their hands with reference alcohol too. After disinfecting to assess the immediate antimicrobial effect a sample as well as pervalue was taken from one random selected hand, unsampled hand was gloved for 3 hours. For the assessment of sustained effect after removing of glove sampling was done as the immediate effect. All bacterial samples were incubated for 24-48h at 37°C±1°C . Between each treatment at least one week had to elapse to allow regrowth of normal skin flora.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013041513017N1**

Registration date: **2013-05-22, 1392/03/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2013-05-22, 1392/03/01

##### Registrant information

###### Name

Mitra Zandiyeh

###### Name of organization / entity

Hamadan medical Sciences university, Paramedical schol

###### Country

Iran (Islamic Republic of)

###### Phone

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##### Recruitment status

###### Recruitment complete

##### Funding source

Vice-chancellor of research, Hamadan University of Medical Sciences

##### Expected recruitment start date

2012-06-02, 1391/03/13

##### Expected recruitment end date

2012-10-01, 1391/07/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison study of antibacterial effectiveness of Betadine-alcohol, Decosept, septicidin and Sterillium for surgical hand anticepcis on hand bacterial flora

#### Public title

Antibacterial effectiveness of Betadine- alcohol, Decosept, septicidin and Sterillium on hand bacterial flora

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

Inclusion criteria: healthy volunteers whose nails were short and clean, and didn't use any substances with antibacterial activity or antibacterial soap for one week before testing Exclusion criteria: pregnant women; presence of any cuts or abrasion on hand skin; any skin disorders.

#### Age

From **18 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **20**

#### Randomization (investigator's opinion)

Not randomized

#### Randomization description

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Other

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

local human subject review board, vice chancellor of research technology, Hamadan university of med

##### Street address

Hamadan university of medical sciences, Shahid Fahmideh Ave

##### City

Hamadan

##### Postal code

6517838736

#### Approval date

2012-05-14, 1391/02/25

#### Ethics committee reference number

3046/9/35/16/پ/د

## Health conditions studied

### 1

#### Description of health condition studied

topical agent

#### ICD-10 code

Y56.9

#### ICD-10 code description

Topical agent, unspecified

## Primary outcomes

### 1

#### Description

Prevalue of microbial culture count

#### Timepoint

After hand washing with soft soap ( before treatment with each product under test)

#### Method of measurement

Fingertrips of each hand for min rub on the base of a petri dish containing 10ml of TSB. dilution of 10-1 and 10-2 of these sampling fluids prepared in TSB . for each dilution 0,1 ml is spread over the surface of a TSA plate. the plates were incubated at 37°C±1°C for 24-48h. Finally the cfu/ml were reported

### 2

#### Description

Immediate postvalue microbial culture count

#### Timepoint

Immediately after treatment with products under test

#### Method of measurement

As well as prevalue microbial culture count , from one hand that was selected randomly

## Secondary outcomes

### 1

#### Description

Three hours post value microbial culture count

#### Timepoint

Three hours after disinfection by product under test

#### Method of measurement

As well as immediate post value microbial culture count , but sample was obtained from another hand( was gloved )

## Intervention groups

### 1

#### Description

Intervention1( treatment with Betadin scrub 7.5%- ethyl alcohol 70%): In accordance with EN12791 before each intervention with every surgical hand disinfectant product under test, volunteers must wash both hands with 10ml soft soap( soap kalinus ) for 1min, then rinsed

with running tap water, subsequently hands were dried with paper towels. After providing prevalue bacterial culture samples, at first subjects wet their hands with tap water, then hands were washed up to wrist in 2, 1.5 min steps as same as EN12791 hand rub technique. In each step 2-3ml betadin was applied. After surgical hand antisepsis, hands were rinsed with tap water for 15 seconds and dried with sterile gauze. Immediately after that, hands were rubbed with 2-3ml ethyl alcohol 70% as hands were kept wet for 1min. Thereupon ; a microbial culture count sample was taken from one randomly selected hand, next another hand was put on sterile glove for 3 hour. From this hand after 3 h, a microbial culture count sample was taken (3 h).

#### **Category**

Treatment - Drugs

### **2**

#### **Description**

Intervention2(treatment with Decosept): In accordance with EN12791 before each intervention with every surgical hand disinfectant product under test, volunteers must wash both hands with 10ml soft soap( soap kalinus ) for 1min, then rinsed with running tap water, subsequently hands were dried with paper towels. After providing prevalue bacterial culture samples, all volunteers disinfected their both hands up to wrist in accordance with EN12791 and standard hand rub procedure with 8-12ml Decosept for 3min. if hands nearly dried, additional volume of product were applied so hands were being kept wet during disinfection period. Thereupon a microbial culture count sample was taken from one randomly selected hand, next another hand was put on sterile glove for 3 hour. From this hand after 3 h, a microbial culture count sample was taken (3 h).

#### **Category**

Treatment - Drugs

### **3**

#### **Description**

Intervention3(treatment with Septicidin): In accordance with EN12791 before each intervention with every surgical hand disinfectant product under test, volunteers must wash both hands with 10ml soft soap( soap kalinus ) for 1min, then rinsed with running tap water, subsequently hands were dried with paper towels. After providing prevalue bacterial culture samples, all volunteers rubbed their both hands up to wrist in accordance with EN12791 and standard hand rub procedure with 10-14ml Septicidin for 6min. as soon as the hands were dried, additional volume of product was used to keep the hands moist while allocate time finished. Thereupon a microbial culture count sample was taken from one randomly selected hand, next another hand was put on sterile glove for 3 hour. From this hand after 3 h, a microbial culture count sample was taken (3 h).

#### **Category**

Treatment - Drugs

### **4**

#### **Description**

Intervention4(treatment with Sterillium): In accordance with EN12791 before each intervention with every surgical hand disinfectant product under test, volunteers must wash both hands with 10ml soft soap( soap kalinus ) for 1min, then rinsed with running tap water, subsequently hands were dried with paper towels. After providing prevalue bacterial culture samples, all volunteers disinfected their both hands up to wrist in accordance with EN12791 and standard hand rub procedure with 4-7ml Sterillium for 3min. if hands nearly dried, additional volume of product were applied so hands were being kept wet during disinfection period. Thereupon a microbial culture count sample was taken from one randomly selected hand, next another hand was put on sterile glove for 3 hour. From this hand after 3 h, a microbial culture count sample was taken (3 h).

#### **Category**

Treatment - Drugs

### **5**

#### **Description**

Intervention5(treatment with reference surgical hand disinfection: Propan- 1- ol 60%): In accordance with EN12791 before each intervention with every surgical hand disinfectant product under test, volunteers must wash both hands with 10ml soft soap( soap kalinus ) for 1min, then rinsed with running tap water, subsequently hands were dried with paper towels. After providing prevalue bacterial culture samples, all volunteers disinfected their both hands up to wrist in accordance with EN12791 and standard hand rub procedure with 6-12ml propan-1-ol 60% for 3min. If hands nearly dried, additional volume of product was applied so hands were being kept wet during disinfection period. Thereupon a microbial culture count sample was taken from one randomly selected hand, next another hand was put on sterile glove for 3 hour. From this hand after 3 h, a microbial culture count sample was taken (3 h).

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Microbiological laboratory of Hamadan university of medical sciences

##### **Full name of responsible person**

Mitra Zandiyeh

##### **Street address**

Shahid Fahmideh Paramedical faculty - Hamadan university of medical sciences

##### **City**

Hamadan

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

vice chancellor for research, Hamadan University of Medical Sciences

**Full name of responsible person**

Dr Heidar Tavilani

**Street address**

vice chancellor for research the Technology, Hamadan university of medical sciences, Shahid Fahmideh Ave, Hamadan

**City**

Hamadan

**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, Hamadan 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**

Hamadan University of Medical Sciences

**Full name of responsible person**

Mitra Zandieh

**Position**

Faculty member of Operating room Department for Paramedical school of Hamadan medical sciences un

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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*