

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of the effect of chlorhexidine, normal saline and nystatin in the prevention of oral candidiasis in patients admitted to the ICU of Tohid Hospital in Sanandaj

#### Protocol summary

##### Study aim

Determining the effect of chlorhexidine, nystatin and normal saline mouthwashes in preventing oral candidiasis in patients admitted to ICU

##### Design

This study is a double-blind randomized clinical trial.

##### Settings and conduct

This study is a double-blind randomized clinical trial to evaluate and compare the effects of nystatin, normal saline and 0.2% chlorhexidine gluconate mouthwashes in the prevention of oral candidiasis. Patients admitted to the ICU of Tohid Teaching Hospital in Sanandaj to be included in the study, using block randomization patients are divided into three groups (5 blocks of 9). In this way, each patient is placed in one of the three groups as soon as he enters the ICU.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients admitted to ICU of Tohid Hospital in Sanandaj exclusion criteria: Clinical observation of oral candidiasis or the presence of more than 50 Candida colonies at the time of admission. The patient's condition is such that he is likely to stay in the ICU for less than 5 days. Existence of any oral diseases  
Lack of patient cooperation until the end of the hospitalization period

##### Intervention groups

Nystatin and chlorhexidine and normal saline

##### Main outcome variables

1. Oral candidiasis 2. Nystatin: is a polynovial mouthwash, a tetramacrolid antibiotic compound. 3. Chlorhexidine: A baseless guanide antiseptic that works against a wide range of bacteria, some fungi, and some viruses. 4. Normal saline: Crystalloid solution containing Na and Cl electrolytes.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170417033483N3**

Registration date: **2020-10-05, 1399/07/14**

Registration timing: **prospective**

Last update: **2020-10-05, 1399/07/14**

Update count: **0**

##### Registration date

2020-10-05, 1399/07/14

##### Registrant information

##### Name

Hero Azizzadeh

##### Name of organization / entity

Kurdistan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 87336646456

##### Email address

h.azizzadeh@muk.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-10-22, 1399/08/01

##### Expected recruitment end date

2021-03-15, 1399/12/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Comparison of the effect of chlorhexidine, normal saline and nystatin in the prevention of oral candidiasis in patients admitted to the ICU of Tohid Hospital in Sanandaj

### Public title

Comparison of chlorhexidine, normal saline, and nystatin in prevention of oral candidiasis in ICU admitted patients of Tohid hospital of sanandaj

### Purpose

Prevention

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Patients admitted to the intensive care unit

#### Exclusion criteria:

Clinical oral candidiasis Existence of more than 50 Candida colonies at the time of admission The patient's condition is such that he is likely to stay in the ICU for less than 5 days. Existence of any oral diseases Lack of patient cooperation until the end of the hospitalization period

### Age

From **14 years** old

### Gender

Both

### Phase

3

### Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

### Sample size

Target sample size: **45**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Block Randomization, Individual, Sealed envelope

### Blinding (investigator's opinion)

Double blinded

### Blinding description

Participant: ICU patients who are not aware of the type of mouthwash they receive. Researcher: The sealed envelopes provided by the statistical consultant to the clinical caregiver and he is not aware of their contents. Outcome Evaluator: A person who does not know the type of mouthwash used by patients and examines the mouth of patients twice a day before giving mouthwash for candidiasis. Data Analyzer: Receives the data extracted from the questionnaires by the researcher and is not aware of the mouthwash received by each patient.

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Kurdistan University of Medical Sciences

##### Street address

Pasdaran St., Shadi hotel in front of., Kurdistan University of Medical Sciences

##### City

sanandaj

##### Province

Kurdistan

##### Postal code

66177-15175

#### Approval date

2015-05-10, 1394/02/20

#### Ethics committee reference number

IR.MUK.REC.1394.67

## Health conditions studied

### 1

#### Description of health condition studied

Oral candidiasis

#### ICD-10 code

B37.0

#### ICD-10 code description

Candidal stomatitis

## Primary outcomes

### 1

#### Description

Oral infection with Candida albicans yeast in more than 50 colonies

#### Timepoint

In 4 stages of admission, on the 5th day and on the 10th and 14th day of admission, sample patients are taken for colony count, respectively.

#### Method of measurement

Patients are forbidden to eat or drink for at least 2 hours before sampling. Sterile swabs are stretched with relatively strong movement on the palate, tongue and cheeks and are immediately transferred to the culture medium.

## Secondary outcomes

### 1

#### Description

Oral diseases

#### Timepoint

Daily every 12 hours  
**Method of measurement**  
observation

## Intervention groups

### 1

#### **Description**

Intervention group: Chlorhexidine mouthwash every 12 hours for 14 days

#### **Category**

Prevention

### 2

#### **Description**

Intervention group: Nystatin mouthwash every 12 hours for 14 days

#### **Category**

Prevention

### 3

#### **Description**

Control group: Normal saline every 12 hours for 14 days

#### **Category**

Prevention

## Recruitment centers

### 1

#### **Recruitment center**

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

Tohid Hospital, Sanandaj

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

Hero azizzadeh

##### **Street address**

Pasdarán St.,

##### **City**

sanandaj

##### **Province**

Kurdistan

##### **Postal code**

66177-13446

##### **Phone**

+98 87 1613 1281

##### **Email**

Heroazizzadeh@yahoo.com

## Sponsors / Funding sources

### 1

#### **Sponsor**

##### **Name of organization / entity**

Sanandaj University of Medical Sciences

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

Hero azizzadeh

##### **Street address**

Pasdarán St.,

#### **City**

Sanandaj

#### **Province**

Kurdistan

#### **Postal code**

66177-13446

#### **Phone**

+98 87 1613 1281

#### **Email**

Heroazizzadeh@yahoo.com

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

Sanandaj 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**

Sanandaj University of Medical Sciences

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

Hero azizzadeh

##### **Position**

General Practitioner

##### **Latest degree**

Medical doctor

##### **Other areas of specialty/work**

General Practitioner

##### **Street address**

Pasdarán St.,

##### **City**

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##### **Province**

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##### **Postal code**

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## Person responsible for scientific inquiries

#### **Contact**

##### **Name of organization / entity**

Sanandaj University of Medical Sciences

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

Hero azizzadeh

**Position**

General Practitioner

**Latest degree**

Medical doctor

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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

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Sanandaj University of Medical Sciences

**Full name of responsible person**

Hero azizzadeh

**Position**

General Practitioner

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

**Street address**