Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 tetramacroloid 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

Pasdaran St.,

City

sanandaj

Province

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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

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Email

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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

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

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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
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Person responsible for updating data

Contact

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Hero azizzadeh

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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