

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jun 2026

### Comparison of green tea and chlorhexidine mouthwash on oral hygiene and bacterial colonies in intubated patients admitted to the intensive care unit.

#### Protocol summary

##### Summary

Abstract Introduction: Throat of a healthy person is a rich environment for growth of different microbes. After 48 hours of hospitalization in intensive patients pharyngeal flora which are gram positive change to gram negative and this may lead to pneumonia. Additionally in patients who undergo mechanical ventilation bacteria leaked around cuff of tracheal tube may causes pneumonia. Objectives: Comparison of the effect of green tea and chlorhexidine mouth wash on oral hygiene and throat bacterial colonies of intubated patients hospitalized in the intensive care unit bandar abbass shahid mohammadi hospital. Methods: This study is a quasi-experimental design and conducted among 46 patients who had mechanical ventilation. Sample patients randomly divided into two groups: according to the crossover method, the first group in the first 4 days day with chlorhexidine solution rinse and 4 second day with a solution of green tea and the second group first 4 days with a solution of green tea mouthwash is second with chlorhexidine solution. Beck instrument has marked and patients oral hygiene were compared.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016020626402N1**

Registration date: **2016-05-29, 1395/03/09**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-05-29, 1395/03/09

##### Registrant information

##### Name

yaser khanchemehr

##### Name of organization / entity

Hormozgan university of medical sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 917 169 5259

##### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

Kerman University of Medical Sciences

##### Expected recruitment start date

2016-04-20, 1395/02/01

##### Expected recruitment end date

2016-07-22, 1395/05/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of green tea and chlorhexidine mouthwash on oral hygiene and bacterial colonies in intubated patients admitted to the intensive care unit.

##### Public title

Mouthwash impact on oral hygiene ICU patients

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: The patient is intubated through the mouth: aged 65-18 years: less than 12 hours of ICU admission time in the past: before admission to the

special section on the other sections have been admitted: avoiding the use of antibiotics before admission: birth control: no history of allergy to herbal substances: lack of dentures: lack of chronic disease and lack of immune disorder: the absence of any damage identified by intubation endotracheal or euros and not unknown in the mouth and around the mouth. Exclusion criteria : The transfer of the patient from the ICU: died before completing his studies: doing any harm identified by intubation or planes or any other physical factors and not wanting to continue the study of the legal guardian of the patient.

**Age**

From **18 years** old to **65 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **46**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Single blinded

**Blinding description****Placebo**

Not used

**Assignment**

Crossover

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Kerman University of Medical Sciences

**Street address**

Central organization of Kerman University of Medical Sciences - After shafa crossroad - Islamic republic boulevard - Kerman - Iran

**City**

Kerman

**Postal code****Approval date**

2016-03-05, 1394/12/15

**Ethics committee reference number**

IR.KMU.REC.1394.651

**Health conditions studied****1****Description of health condition studied**

mucositis

**ICD-10 code**

K12.3

**ICD-10 code description**

Oral mucositis (ulcerative)

**Primary outcomes****1****Description**

Oral hygiene

**Timepoint**

The first day of intervention and fourth day of intervention and eighth day of intervention

**Method of measurement**

Beck oral assessment Scale And Culture of throat secretions

**Secondary outcomes****1****Description**

Mouth and throat infection. Plaque

**Timepoint**

The first day of intervention and fourth day of intervention and eighth day of intervention

**Method of measurement**

Culture of throat secretions, mucosal plaque score

**Intervention groups****1****Description**

According to the crossover method, the first group in the first 4 days with chlorhexidine solution mouthwash and 4 second days with a solution of green tea and the second group first 4 days with a solution of green tea and 4 second days with chlorhexidine solution mouthwash done. In this study patients (cases) their own controls Are. The first group in the first place by using chlorhexidine solution and a soft toothbrush tooth surfaces and tongue from back to front and rotational movements cleaned, followed by 10 ml of solution of chlorhexidine 2% in the oral cavity molding and after mouthwash green tea 5% mouthwash will thus using a solution of mouthwash green tea and a soft toothbrush levels tongue and teeth from back to front and rotational movements dirty will be cleaned at the end of day 8, recultivation from the throat of the patient is sent. In all the steps and distance between Beck and MPS mouthwash oral health assessment form will be filled. In the second group in the first stage using a solution of green tea and a soft toothbrush tooth surfaces and tongue from back to front and rotational movements cleaned, followed by 10 ml of solution mouthwash green tea 5% in the oral cavity molding and after a suction

minutes throat and mouth area is performed the steps of the work for twice daily and continues for four days and again at the end of the fourth day of culture sterile technique taken from the throat area and will be sent to the shahid mohammadi hospital laboratory and the complete check list is oral hygiene. In the second phase patient for 4 days with chlorhexidine solution and a soft toothbrush and tongue from back to front tooth surfaces can be cleaned with rotational movements followed by 10 cc of spilled solution of chlorhexidine in the oral cavity and pharyngeal area and after a minute oral suction is performed. At the end of day 8 of culture from the throat to sterile technique and will be sent to the laboratory.

**Category**

Prevention

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Bandar Abbas shahid Mohammadi hospital

**Full name of responsible person**

yaser khanchemehr

**Street address**

Shahid Mohammadi hospital

**City**

Bandar Abbas

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Hakimeh hossein rezaei

**Street address**

Kerman , Razi Nursing College

**City**

Kerman

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Kerman 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**

Kerman University of Medical Sciences

**Full name of responsible person**

Yaser khanchemehr

**Position**

Master Degree

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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*