Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of nasal care with 0.9% sodium chloride spray on pharyngeal colonization and nasal discharge in patients undergoing mechanical ventilation in intensive care units

Protocol summary

Study aim
The effect of nasal care with 0.9% sodium chloride spray on pharyngeal colonization and nasal secretions in patients undergoing mechanical ventilation in intensive care units

Design
The clinical trial has two intervention and control groups, with parallel, blinded, randomized

Settings and conduct
Patients in the intensive care unit of Bahonar Hospital of Kerman who were included in the study were divided into intervention and control groups by convenience sampling. Background information questionnaire was completed by patients. Nasal secretions and frequency and type of throat colonies were studied.

Participants/Inclusion and exclusion criteria
Inclusion: No infection with mouth and lungs before starting study with doctor's diagnosis No sinusitis on arrival at diagnosis with a physician No fractures of the face and nose Complete occlusion of the nostril Absence of subglottic endotracheal tube; Exclusion: Patient transfer from ICU before completion of study Patients with less than 10 days' hospitalization

Intervention groups
In the nasal care group, in addition to routine care, a 0.9% saline spray is sprayed in both nostrils four times a day concurrently with routine care by the nurse, and in the control group only routine care is provided by the nurse for 10 days. . Nasal discharge and pharyngeal colonization of the patient before, day 5 of intervention and day 10 of intervention are evaluated using clinical examination and sample culture.

Main outcome variables
Nasal care with 0.9% sodium chloride spray on throat colonization; Nasal care with 0.9% sodium chloride spray on nasal secretions

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170116031972N8**
Registration date: **2019-08-22, 1398/05/31**
Registration timing: **prospective**

Last update: **2019-08-22, 1398/05/31**
Update count: **0**

Registration date
2019-08-22, 1398/05/31

Registrant information

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Mahlagha Dehghan Anari

Name of organization / entity
Kerman University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-08-23, 1398/06/01

Expected recruitment end date
2019-11-22, 1398/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The effect of nasal care with 0.9% sodium chloride spray on pharyngeal colonization and nasal discharge in patients undergoing mechanical ventilation in intensive care units

Public title
The effect of nasal care with 0.9% sodium chloride spray on pharyngeal colonization and nasal secretions in patients undergoing mechanical ventilation
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Under aggressive mechanical ventilation Less than 12 hours have passed since the patient entered the ward No diagnosis of oral and lung infection before starting study with physician diagnosis No sinusitis on arrival at diagnosis with a physician No fractures of the face and nose Complete occlusion of the nostril Absence of subglottic endotracheal tube
Exclusion criteria:
Transfer the patient from the ICU before completing the study Patients with less than 10 days' hospitalization
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
1
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Available randomization, block allocation
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Kerman University of Medical Sciences Ethics Committee
Street address
Campus of the University of Medical Sciences, the beginning of the axis of the seven Alavi gardens
City
Kerman
Province
Kerman
Postal code
7616913555
Approval date
2019-07-29, 1398/05/07
Ethics committee reference number
IR.KMU.REC.1398.220

Health conditions studied

1

Description of health condition studied
The effect of nasal care with 0.9% sodium chloride spray on pharyngeal colonization and nasal secretions in patients undergoing mechanical ventilation in intensive care units
ICD-10 code
J34.8
ICD-10 code description
Other specified disorders of nose and nasal sinuses

Primary outcomes

1

Description
Effect of nasal care with 0.9% sodium chloride spray on throat colonization and nasal secretions
Timepoint
In the control group, mouthwash is administered with 0.2% chlorhexidine solution every 6 hours (4 times a day 6/12_18_24). In the intervention group (nasal care) In addition to receiving routine care, an isotonic saline spray puff (0.9%) was sprayed by the nurse simultaneously with mouthwash four times daily in both nostrils for 10 days.
Method of measurement
Background information questionnaire and nasal discharge survey and sampling of throat discharge are used for data collection.

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Only routine care in the intensive care unit is provided by the nurse. In this group oral rinse with 0.2% chlorhexidine solution every 6 hours (4 times a day 6_12_18_24). Nasal secretions by a nurse who is not aware of specimens assigned to the groups and throat culture by sampling the throat secretions, before study

(morning shift before routine care and intervention), end of day 5 (morning shift). Sixth day before routine care and intervention) and end of day 10 (11th morning shift before routine care).

Category

Treatment - Drugs

2

Description

Intervention group: Intervention group: In this group, in addition to the usual care, an isotonic saline spray (0.9%) was sprayed by the nurse at both nostrils four times daily for 10 days by both nostrils. The time to start the study and cultivate the first time is in the morning shift before the usual care and spraying of saline is started. And how the researcher does it correctly is explained orally. Nasal secretion type by a nurse who is not aware of the specimens assigned to the groups and throat culture by sampling the throat secretions, before the study (morning shift before routine care and intervention), end of day 5 (shift Sixth morning before routine care and intervention) and end of day 10 (11th morning shift before routine care).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Bahonar Hospital of Kerman

Full name of responsible person

Mehrnoosh eghtedarnejad

Street address

Bahonar Hospital, Gharani Street

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Kerman

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Abbas Pardakhti

Street address

Campus of the University of Medical Sciences, the beginning of the axis of the seven Alavi gardens

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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

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Mehrnoosh Eghtedarnejad

Position

Masters

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

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Person responsible for scientific inquiries

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Position

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Person responsible for updating data

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Full name of responsible person

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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