Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison the effect of hydrocolloid with film dressing on prevention of pressure ulcer caused by O2 therapy equipment in patients in critical care units

Protocol summary

Study aim
Comparison the effect of hydrocolloid with film dressing on prevention of pressure ulcer caused by O2 therapy equipment in patients in critical care units

Design
Two arm parallel group randomised trial with blinded postoperative care and outcome assessment

Settings and conduct
After selecting the sample, they will randomly the right ear is used by the dressing of the hydrocolloid, and in the transparent film dressing group, the transparent film dressing will be used to cover the right ear of the patient.In both groups, the left ear is considered as control. The location of the dressing of both ears in both groups is investigated by a trained person without any knowledge of the study objective twice a day r. The intervention will continue for 3 days .

Participants/Inclusion and exclusion criteria
Having informed consent to attend research The need for oxygen therapy for more than two hours through nasal cannula and facial mask Age older than 18 years The absence of ulcers in the patient's ears and having healthy ears Cancellation of the patient, but the patient's cure at any time of the study Discontinue oxygen therapy during the study according to the physician's order Discharge or transfer of patient

Intervention groups
the research sample is easy and based on the goal, according to the input criteria, it will be divided into two groups of easy hydrocolloid dressing by simple random method. the right ear is considered as an intervention and the left ear is considered as control.

Main outcome variables
Comparison of the effect of two dressings on the prevention of compression caused by medical equipment due to the difference in the production of pressure ulcers caused by oxygen therapy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190320043094N1**
Registration date: **2019-04-01, 1398/01/12**
Registration timing: **prospective**

Last update: **2019-04-01, 1398/01/12**
Update count: **0**

Registration date
2019-04-01, 1398/01/12

Registrant information

Name
Neda Sabahi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 5722 3028

Email address
nedasabahi123@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-04-21, 1398/02/01

Expected recruitment end date
2019-06-22, 1398/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison the effect of hydrocolloid with film dressing on prevention of pressure ulcer caused by O2 therapy equipment in patients in critical care units

Public title
Comparison the effect of hydrocolloid with film dressing on prevention of pressure ulcer caused by O2 therapy equipment in patients in critical care units

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Having informed consent to attend research The need for oxygen therapy for more than two hours through nasal cannula and facial mask Age older than 18 years The absence of ulcers in the patient's ears and having healthy ears
Exclusion criteria:
Cancellation of the patient, but the patient's cure at any time of the study Discontinue oxygen therapy during the study according to the physician's order Discharge or transfer of patient

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
In this research, the research sample was easy and based on the purpose of the selected entry criteria and then the method Easy randomization will be divided into two groups of hydrocolloid and transparent dressing. In each group, the right ear is as an intervention The left ear will be considered as control.

Blinding (investigator's opinion)
Double blinded

Blinding description
In the patients of the hydrocolloidal dressing group, the right ear is used by the dressing of the hydrocolloid, and in the transparent film dressing group, the transparent film dressing will be used to cover the right ear of the patient. In both groups, the left ear is considered as control. The location of the dressing of both ears in both groups is investigated by a trained person without any knowledge of the study objective twice a day and recorded in the monitoring checklist of the pressure ulcer.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethnical CommitEthnical Committee of Gonabad University of Medical Sciences
Street address
Imam Khomeini Street, Gonabad University of Medical Sciences
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Approval date
2019-03-26, 1398/01/06

Ethics committee reference number
IR.GMU.REC.1397.131

Health conditions studied

1

Description of health condition studied
pressure ulcer

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Pressure ulcer

Timepoint
The effect of hydrocolloid dressing and film cloth will be checked for three days and twice a day.

Method of measurement
Braden Scale

Secondary outcomes

1

Description
Braden Scale

Timepoint
Before the intervention begins

Method of measurement
Braden Scale

Intervention groups

1

Description
Intervention group: Intervention group: The first intervention group consisted of hydrocolloid dressing and the second intervention group, including transparent film dressing and control group
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Nohom day hospital
Full name of responsible person
Neda Sabahi
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Parastar Ave- Nohom day hospital
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Sponsors / Funding sources

1

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Name of organization / entity
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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
Gonabad 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
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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