

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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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Province

Razavi Khorasan

Postal code

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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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

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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

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Neda Sabahi

Position

Master of science

Latest degree

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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