Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Sep 2026

Effect of touch on patients’ agitation under mechanical ventilation

Protocol summary

Summary

The aim of this study is to determine the effect of touch on patient's agitation under mechanical ventilation. Inclusion criteria: Alert patient between 30- 60 years old with acute respiratory problems and under mechanical ventilation with agitation, which assessed with Richmond criteria. If the level of agitation was, +2 - +4 this case inter to study. Exclusion criteria of study: If a patient feels comfortable after primary nursing care, and agitation behavior is controlled, or by any reason the patient is separated from mechanical ventilation the patient is excluded from study. The society of under study: Our samples include of patients, which hospitalized in ward of intensive care unit in Tehran Day hospital, that have inter criteria situation. Sample size: Will be assessing 30 patients. Time and type of intervention and primary consequence: Application of intervention is in two forms that consequences of them allocation in randomize. First intervention: With standing beside the patient and use of touch in form of therapist's palm hand contact to behind the patient's wrist (So that therapist's fingers become close in the internal part of the patient's forearm) and without pressure use, touch will take for five minutes. Other intervention: Nurse only stands beside the patient for five minutes, without touching him. Patient's agitation scores evaluate and record before and after each intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201104276318N1**
Registration date: **2011-07-11, 1390/04/20**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-07-11, 1390/04/20

Registrant information

Name
Monir Nobahar
Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Semnan University of Medical Sciences

Expected recruitment start date

2011-04-25, 1390/02/05

Expected recruitment end date

2011-07-27, 1390/05/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of touch on patients’ agitation under mechanical ventilation

Public title

Effect of touch on patients’ agitation

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria : Alert patient between 30- 60 years old with acute respiratory problems and under mechanical ventilation with agitation, which assessed with Richmond criteria. If the level of agitation was, +2 - +4 this case inter to study. Exclusion criteria of study: If a patient feels comfortable after primary nursing care, and

agitation behavior is controlled, or by any reason the patient is separated from mechanical ventilation the patient is excluded from study.

Age
From **30 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Semnan University of Medical Sciences

Street address
Boulvar Basij, Semnan

City
Semnan

Postal code

Approval date
2010-08-20, 1389/05/29

Ethics committee reference number
89.49280

Health conditions studied

1

Description of health condition studied
Agitation

ICD-10 code
R45.1

ICD-10 code description

Primary outcomes

1

Description
Agitation

Timepoint
5 min

Method of measurement
The tool of agitation assessment is Richmond, which according to the mood and amount of violence, type of limbs purposeful movements and the dangerous actions existence evaluate the patient alertness and response to commands and determine the level of patient agitation.

Secondary outcomes

1

Description
Agitation

Timepoint
5 min

Method of measurement
The tool of agitation assessment is Richmond, which according to the mood and amount of violence, type of limbs purposeful movements and the dangerous actions existence evaluate the patient alertness and response to commands and determine the level of patient agitation.

Intervention groups

1

Description
First intervention: With standing beside the patient and use of touch in form of therapist's palm hand contact to behind the patient's wrist (So that therapist's fingers become close in the internal part of the patient's forearm) and without pressure use, touch will take for five minutes.

Category
Other

2

Description
Other intervention: Nurse only stands beside the patient for five minutes, without touching him. Patient's agitation scores evaluate and record before and after each intervention.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Tehran Day Hospital

Full name of responsible person
Nobahar Monir

Street address
Tehran

City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Dr. Ghorbani
Street address
Semnan
City
Semnan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Semnan 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
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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