

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

Semnan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

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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**Name of organization / entity**

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Full name of responsible person

Nobahar Monir

Position

Academic member

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Instructor

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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