Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Jun 2026

Comparison of the effect of two upper limb physical restraint type on the clinical outcomes of children under mechanical ventilation: A crossover randomized clinical trial study

Protocol summary

Study aim

Determining and comparing the local consequences of restraint and the degree of agitation in children under mechanical ventilation in 2 methods of restraint at assessment times

Design

It is a single-blind crossover trial on 48 patients. Available sampling and use of Rand List software and use of matte envelope

Settings and conduct

The pediatric icu of Tabriz Children's Educational and Medical Center One-sided blindness of the study due to the age and clinical condition of the participants

Participants/Inclusion and exclusion criteria

Children aged 1 to 5 years; Being hospitalized in the pediatric icu; Being under mechanical ventilation; The Physician order to use physical restraint in the upper limbs; The consent of the child's parents No entry conditions: Existence of intra venous line in both upper limbs; Instability of the child's physiological condition before the intervention; Children with hemiplegia, extensive hematoma, history of surgery or trauma, casts or splints in restrained limbs

Intervention groups

For group A, first wrist restraint and then elbow restraint will be used. In group B, first the elbow is restrained and then the wrist is restrained. The duration of all restraints is 2 hours. Due to the routine physical restraint in the ward and to eliminate the effect of restraint, before the intervention, 15 minutes will be considered as a wash out period and the child will be continuously and directly monitored by the researcher. He will not be restrained, and during this time the researcher will prevent it if he observes the child trying to pull the equipment by keeping the limb calm. During the intervention in both groups, a 15-minute cleansing period will be considered to eliminate the restraint effect after each of the restraints.

Main outcome variables

Palm temperature; Number of radial pulses; Edema of the hand; Clinical erythema of the hand; The degree of agitation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200818048448N2**
Registration date: **2022-06-08, 1401/03/18**
Registration timing: **prospective**

Last update: **2022-06-08, 1401/03/18**
Update count: **0**

Registration date

2022-06-08, 1401/03/18

Registrant information

Name

Mahni Rahkar Farshi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-15, 1401/03/25

Expected recruitment end date

2022-10-17, 1401/07/25

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of two upper limb physical restraint type on the clinical outcomes of children under mechanical ventilation: A crossover randomized clinical trial study

Public title
Comparison of the effect of two upper limb physical restraint type on the clinical outcomes of children under mechanical ventilation
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria:
Children aged 1 to 5 years Being hospitalized in the pediatric intensive care unit Being under mechanical ventilation Physician order to use physical restraint in the upper limb The consent of the child's parents
Exclusion criteria:
Existence of intra venous line in both upper limbs Instability of the child's physiological condition before the intervention Children with hemiplegia, extensive hematoma, history of surgery or trauma in the restrained limb Children with casts or splints in restrained limbs
Age
From **1 year** old to **5 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **48**
Randomization (investigator's opinion)
Randomized
Randomization description
Eligible children will be selected by available sampling method and will be randomly divided into two groups A and B by using Rand List software. The random sequence created will be covered using matte envelopes, and the envelopes will be given to the researcher in order of number, and after opening the envelope, the child's group will be determined.
Blinding (investigator's opinion)
Single blinded
Blinding description
Participants in this study are children who, due to age and clinical condition, will not have real knowledge of the type of intervention performed.
Placebo
Not used
Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Faculty of Nursing and Midwifery, South Shariati Ave. Tabriz, Iran
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Tabriz
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East Azarbaijan
Postal code
5143377505
Approval date
2022-01-12, 1400/10/22
Ethics committee reference number
IR.TBZMED.REC.1400.1039

Health conditions studied

1

Description of health condition studied
agitation sedation level
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
erythema
Timepoint
Measurements before the intervention will be reviewed and recorded after the initial cleansing period and before the intervention begins. Measurement during the intervention will be done one hour after the start of the intervention and measurement after the intervention will be performed immediately after the end of the two hours of the intervention.
Method of measurement
clinician erythema assessment

2

Description
Edema of the hand
Timepoint
Measurements before the intervention will be reviewed and recorded after the initial cleansing period and before the intervention begins. Measurement during the

intervention will be done one hour after the start of the intervention and measurement after the intervention will be performed immediately after the end of the two hours of the intervention.

Method of measurement

Figure-of-Eight Method of Measuring Hand

3

Description

Palm temperature

Timepoint

Measurements before the intervention will be reviewed and recorded after the initial cleansing period and before the intervention begins. Measurement during the intervention will be done one hour after the start of the intervention and measurement after the intervention will be performed immediately after the end of the two hours of the intervention.

Method of measurement

Digital thermometer

4

Description

Radial pulse

Timepoint

Measurements before the intervention will be reviewed and recorded after the initial cleansing period and before the intervention begins. Measurement during the intervention will be done one hour after the start of the intervention and measurement after the intervention will be performed immediately after the end of the two hours of the intervention.

Method of measurement

Manually count the number of radial pulses per minute

5

Description

Agitation and sedation

Timepoint

Measurements before the intervention will be reviewed and recorded after the initial cleansing period and before the intervention begins. Measurement during the intervention will be done one hour after the start of the intervention and measurement after the intervention will be performed immediately after the end of the two hours of the intervention.

Method of measurement

Richmond Agitation-Sedation Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For group A, first wrist restraint will be done for two hours and then elbow restraint will be done for two hours. Due to the physical restraint performed routinely and to eliminate the effect of restraint, before the intervention, a period of 15 minutes will be considered as a wash out period and the child will be observed by the executive researcher under continuous and direct observation and without restraint. During this time, the researcher will prevent the child from trying to pull the equipment by keeping the limb calm. To restrain the wrist, medical gauze three to five centimeters wide (depending on the child's body) will be used, inside which a cotton roll will be placed. A roll of gauze and cotton is wrapped around the wrist and a long strip of gauze is tied from one end around the roll and from the other end to the bed in the form of the number eight. To prevent pressure on the limb, a distance of one finger (index finger) will be considered between the gas roll and the skin. To apply elbow restraint, two splints with pads, one below and one on the elbow joint, will be used. Then the upper part of the splints on the arm side and the lower part of the splints on the forearm side will be closed using two separate gas strips. In this way, the gas strip is wrapped around the splints and limbs and will be fastened on the upper splint with a simple knot. To prevent pressure on the limb, a distance of one finger (index finger) will be considered between the gas strip and the skin. The size of the splints used will be chosen based on the child's body so that it covers the upper and lower thirds of the elbow joint.

Category

Other

2

Description

Intervention group: For group B, after a 15-minute wash-out time, first the elbow is restrained for two hours and then the wrist is restrained for two hours. The method of applying wrist and elbow restraint will be the same as the method applied in group A intervention.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mardaniazar Medical Center

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor
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
Tabriz 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

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Study protocol Informed consent form

When the data will become available and for how long

The access time will start 6 months after the results are published.

To whom data/document is available

The data will only be available to researchers working at academic institutions.

Under which criteria data/document could be used

Researchers working in academic institutions are allowed to request documentation.

From where data/document is obtainable

Refer to the person responsible for the general response of the trial.

What processes are involved for a request to access data/document

The request is sent to the person in charge of the trial and with the coordination of the research vice chancellor of the university, documents will be sent.

Comments