Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The Effect of Presence of Clown on the Anxiety and Pain of 3 to 12 Years Old Hospitalized Children in the Pediatric Intensive Care Unit(s) Throughout Weaning Process from Mechanical Ventilation,

Protocol summary

Study aim

Determine the effect of clown's presence on anxiety and pain in children aged 3 to 12 years in intensive care units during the weaning process of the mechanical ventilation.

Design

This study is a quantitative interventional study of randomized clinical trial (assigning children with milk or line entry criteria randomly to two groups of intervention and control), which was conducted in the Children's Care Unit and Emergency Care Unit Hospital of Children's Medical Center of Iran. Sample size will be allocated to statistical estimates after pilot study implementation.

Settings and conduct

in the Children's Care Unit and Emergency Care Unit of the Children's Medical Center Hospital in Iran.

Participants/Inclusion and exclusion criteria

- Under mechanical ventilation during the weaning. - Healthy Children for Cognition, Vision and Hearing, GCSS Higher than / equal 8, Appropriate Conciseness Level According to PICU Pediatrician, 3-12 age Children, and Both gender(Female and Male

Intervention groups

1 hour before the first action for weaning in the control and intervention groups. Then, in the intervention group, clown doctors contact with the parent of the patient for 15 minutes, starting joke with the puppet and the patient's gaming devices to establish trust in the child. After building the truth ,clowns using their own skills,support and fun interventions based on the age and interest of the child for 15 Minutes. The child's tube trachea removed by the doctor. clowns will be present again 15 minutes after weaning. The children in the control group receive routine care.COMFORT pain scale and RASS scale, vital signs of the child, GCS, type and dosage of the received drugs are recorded between stages and after 1 hour weaning, by researcher

Main outcome variables

Relieve pain and anxiety of the child in the process of weaning mechanical ventilation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180429039464N1**
Registration date: **2018-10-20, 1397/07/28**
Registration timing: **retrospective**

Last update: **2018-10-20, 1397/07/28**
Update count: **0**

Registration date

2018-10-20, 1397/07/28

Registrant information

Name

Marzieh Hasanpour

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-05, 1397/02/15

Expected recruitment end date

2018-10-07, 1397/07/15

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effect of Presence of Clown on the Anxiety and Pain of 3 to 12 Years Old Hospitalized Children in the Pediatric Intensive Care Unit(s) Throughout Weaning Process from Mechanical Ventilation,

Public title
The Effect of Presence of Clown on the Anxiety and Pain of 3 to 12 Years Old Hospitalized Children in the Pediatric Intensive Care Unit(s) Throughout Weaning Process from Mechanical Ventilation,
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Children Under Mechanical Ventilation Throughout Weaning Pro. Healthy Children for Cognition, Vision and Hearing Appropriate Conciseness Level According to PICU Pediatrician, GCSS Higher than / equal 8 3-12 age Children, and Both gender(Female and Male)
Exclusion criteria:
History of Sensory and Mental Disturbances Specially Anxiety Nervous Disorders receiving sedative drugs having developmental delay disorders any kind of fear to clowns the parents or child's unwillingness at each stage of the study
Age
From **3 years** old to **12 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Random Allocation to Intervention and Control Group by Chance and Give Odd and Even Number to Each Patient
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of School of Nursing and Midwifery & Rehabilitation - Tehran University of
Street address
School of Nursing and Midwifery of Tehran, Tohied Sq. Dr Mirkhani St(East Nosrat)
City
Tehran
Province
Tehran
Postal code
1419733171
Approval date
2018-04-22, 1397/02/02
Ethics committee reference number
IR.TUMS.FNM.REC.1396.4353

Health conditions studied

1

Description of health condition studied
Pain and Anxiety of Hospitalized Ventilated Children in PICU
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The Severity of Pain is the average score that is obtained using the COMFORT Pain Scale
Timepoint
One hour before weaning, 45 minutes before weaning, half an hour before weaning, after weaning, 15 minutes after weaning, an hour after weaning.
Method of measurement
COMFORT Pain Scale

2

Description
Anxiety is the mean scores of anxiety symptoms using the RASS Scale.
Timepoint
One hour before weaning, 45 minutes before weaning, half an hour before weaning, after weaning, 15 minutes after weaning, an hour after weaning.
Method of measurement
RASS Scale

Secondary outcomes

empty

Intervention groups

1

Description
In the intervention group, the clowns interact with the parent of the patient for 15 minutes, distance from the child, and start their jokes with the puppet and the patient's gaming devices to establish trust in the child. After creating the trust, using their skills, interventions are performed based on the age and the child's interests for 15 minutes. then the child's tube trachea is removed by the doctor. Clowns will be on the patient's bedside for 15 minutes after weaning .

Category
Behavior

2

Description
Control group: The children in the control group receive routine care. The COMFORT pain scale and the RASS scale, the child's vital signs, descriptive level of consciousness, and GCSS, the type and dosage of the medications received by the patient between each step and one hour after separation are recorded by the researcher.

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Children's Medical Center Hospital

Full name of responsible person
Dr. Shervin Badv

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Children's Medical Center Hospital, Gharib Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
Vida Kardan Moghaddam

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Grant name

Grant code / Reference number
20000000

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Tehran University of Medical Sciences

Proportion provided by this source
40

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
Tehran University of Medical Sciences

Full name of responsible person
Dr Marzieh Hasanpour

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Person responsible for updating data

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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