

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 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)

##### Phone

+98 21 6105 4413

##### Email address

m-hasanpour@sina.tums.ac.ir

##### 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

#### Street address

Children's Medical Center Hospital, Gharib Ave

#### City

Tehran

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#### Postal code

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#### Phone

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#### Web page address

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Vida Kardan Moghaddam

#### Street address

School of Nursing Midwifery, Tehran University of

Medical Sciences, Mirkhani St, Tohid Squ.

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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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School of Nursing and Midwifery of Tehran, Mirkhani St, Tohid Square

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

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**Email**

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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