

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of bubble therapy on anger and anxiety in Children with seizures hospitalized

Protocol summary

Study aim

Determining the effect of bubble-making game therapy on the level of anger and anxiety in hospitalized children with seizures

Design

Clinical trial with intervention and control group, single-blind, randomized, phase 3 on 60 patients. For randomization, odd numbers will correspond to the control group and even numbers will correspond to the intervention group..

Settings and conduct

The intervention was performed in children 8-12 years of age with seizures hospitalized in two hospitals in Karaj. The severity of anger and anxiety in a child with epilepsy was measured by the researcher with the Anger and Anxiety Scale 5 minutes before the start and 5 minutes after the venipuncture and was compared and recorded with the answers to the initial questionnaire. In the control group, the same measures were performed without a bubble maker

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 8-12 years old. Children with convulsions hospitalized, Parental consent, The second and third day of hospitalization, Children who are not being treated for anxiety or anger. Exclusion criteria: Child discharge, Child malnutrition, Children with high levels of anxiety and anger

Intervention groups

In the intervention group, the bubble machine was given to the child by the researcher 5 minutes before the insertion of the vein by the nurse and 5 minutes after that, and the insertion of the vein will be done by a nurse, then the intensity of anger and anxiety of the child with epilepsy 5 minutes before the start And 5 minutes after taking the vein, it will be measured by the researcher with the scale of anger and anxiety and will be compared and recorded with the answers of the initial questionnaire. Routine procedures will be performed in the control group.

Main outcome variables

Anger and anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210129050175N1**

Registration date: **2023-10-03, 1402/07/11**

Registration timing: **retrospective**

Last update: **2023-10-03, 1402/07/11**

Update count: **0**

Registration date

2023-10-03, 1402/07/11

Registrant information

Name

Leyla Ebrahimpour somarin

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3456 2980

Email address

ebrahimpour.14736@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-11, 1401/08/20

Expected recruitment end date

2022-12-11, 1401/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of bubble therapy on anger and anxiety in Children with seizures hospitalized

Public title

The effect of bubble therapy on anger and anxiety in children

Purpose

Other

Inclusion/Exclusion criteria**Inclusion criteria:**

The child is hospitalized on the second and third day. Children who are not being treated and followed up for anxiety or anger. Children aged 12-8 years Children with seizures hospitalized Parent and child satisfaction based on the presence of the child in the research

Exclusion criteria:**Age**

From **8 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling in this research was done in such a way that the samples were made available in a purposeful way in order to include children in the research and were randomly divided into two control and intervention groups. During vein sampling, the odd numbers related to the control group and the even numbers related to the intervention group were included.

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants are blinded because similar problems would arise if the patient knew what treatment she was receiving.

Placebo

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Islamic Azad University, Medical Sciences Branch of Tehr

Street address

The corrected address is: "Headquarters Building of Tehran Islamic Azad University of Medical Sciences, Gol Yakh St. corner, Ayane Blvd., Golhak Du Rahi, Amir Pabarja St., Dr. Shariati St., Tehran."

City

Tehran

Province

Tehran

Postal code

3195637839

Approval date

2021-07-13, 1400/04/22

Ethics committee reference number

IR.IAU.TMU.REC.1400.235

Health conditions studied**1****Description of health condition studied**

Convulsions

ICD-10 code

F06.4

ICD-10 code description

Anxiety disorder due to known physiological condition

Primary outcomes**1****Description**

Anger and anxiety

Timepoint

5 minutes before and 5 minutes after venipuncture

Method of measurement

Nelson Anger Scale and Spielberger Anxiety Inventory

Secondary outcomes

empty

Intervention groups**1****Description**

In the intervention group, a "bubble maker" provided by the researcher was used from five minutes before the nurse's vein insertion until five minutes afterward for the hospitalized child with seizures. The child was allowed to play with one hand during the vein insertion.

Category

Treatment - Devices

2**Description**

In the control group, a nurse with expertise in

venipuncture conducted the procedure in a standard ward without any additional intervention. The child's levels of anger and anxiety were assessed by the researcher using an anger scale, both 5 minutes before and after the venipuncture. The control group's anxiety levels were also measured and recorded.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali and Sarollah Hospital

Full name of responsible person

Ms Akhtar

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Imam Ali Hospital, Chalous Street

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2

Recruitment center

Name of recruitment center

Sarollah Hospital

Full name of responsible person

Maryam Hassanpour

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Tahereh Nasrabadi

Street address

Tehran, Dr. Shariati St., Gholhak Intersection, Amir Paberja St., Mirror Blvd.

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Islamic Azad University

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

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Ms.sepide Nasrullah

Position

Head of Educational Deputy

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Leyla Ebrahimpour

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information.

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

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

Islamic Azad University

Full name of responsible person

Leyla Ebrahimpour

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery