

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effects of deep breathing, feet off the gig and combining them on intensity of venipuncture pain and Heart Rate and Pulse Oximetry in school age children-A randomized clinical trial

Protocol summary

Study aim

1- Comparison of pain intensity changes in the four groups before and after the intervention 2- Comparison of heart rate changes in the four groups before and after the intervention

Design

The sample size will be 64 children. By random sampling, 16 children will be placed in each of the four groups, each with 8 girls and 8 boys, randomly divided into four groups: 1. Deep breathing with deep feet. 2. Deep breathing. 3. Depth of foot. 4) Control will be, the sample size will be 16 in each group. In each of the 4 groups, the pain intensity and physiological indices will be measured 3 minutes before and 3 minutes after placement.

Settings and conduct

6-12 years old children referred to the Emergency Hospital of Imam Hossein Harris Hospital, who are diagnosed with a doctor, need to have an intravenous line for them, were randomly divided into four groups: 1. Deep breathing with deep feet. 2. Deep breathing. 3. Death. The gig 4) control. In each of the 4 groups, pain intensity and physiological indices will be measured 3 minutes before and 3 minutes after sedation. In groups 1, 2 and 3, one minute before the venipuncture, Deviation of thought will be done. In groups 1, 2 and 3, one minute before placement, a deviation of thought will be made, which in group 1, will be performed by a deep tail with a nose and at the top of the gingival. In group 2, a deep tail with a nose and exhale will be in the mouth. In group 3, only the ridge will die, and in groups 1 and 3, after the spin in the gig and in group 2, after exhalation, the numbers will be counted up to 10 spins or 10 respiration. The tracking will be done before the end of counting the numbers. In the control group, there will be no intervention, the data will be analyzed after the collection using SPSS22 software

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. The age of the child is 12-6 years old. 2. Be able to count numbers from 1 to 10. 3. The child is alert that there is a possibility of question and answer. 4. Children and parents are willing to cooperate. Exit criteria: 1. Having any life-threatening illness 2. Use of pain relief 3. Catheter insertion more than once into the skin 4. Use of sedative drugs and anticonvulsants

Intervention groups

1) Deep breathing with a finned foot. 2) Deep breathing. 3) Footsteps. 4) control,

Main outcome variables

Changes in pain intensity; changes in heart rate; changes in SPO2

General information

Reason for update

Acronym

-

IRCT registration information

IRCT registration number: **IRCT20130617013691N9**

Registration date: **2018-01-11, 1396/10/21**

Registration timing: **retrospective**

Last update: **2018-01-11, 1396/10/21**

Update count: **0**

Registration date

2018-01-11, 1396/10/21

Registrant information

Name

Mohammad Arshadi Bostanabad

Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Tabriz University of medical sciences research

Expected recruitment start date

2016-05-06, 1395/02/17

Expected recruitment end date

2017-06-07, 1396/03/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of deep breathing, feet off the gig and combining them on intensity of venipuncture pain and Heart Rate and Pulse Oximetry in school age children-A randomized clinical trial

Public title

The effects of deep breathing, feet off gig and combining them on intensity of venipuncture pain and physiological parameters in school age children-A randomized clinical trial

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

The child is 12-6 years of age. The cadence is to count the numbers from 1 to 10. A child is aware that there is a possibility of questions and answers. Children and parents tend to cooperate.

Exclusion criteria:

Having any life-threatening illness Use Housing to relieve pain Catheter more than once into the skin Taking sedative medications and anticonvulsants

Age

From **6 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Random sampling will be available, so that by using a randomized table, children will be randomly assigned to one of four groups. Assignment Sequences are determined using a computer random number table (www.Random.com), and in order to hide the allocation, the opaque packets are numbered sequentially.

Blinding (investigator's opinion)

Not blinded

Blinding description

No blinding

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Tabriz University of Medical Sciences

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South Sharyati Ave

City

Tabriz

Province

East Azarbaijan

Postal code

-

Approval date

2017-05-22, 1396/03/01

Ethics committee reference number

IR.TBZMED.REC.1396.171

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

Pain intensity

ICD-10 code

R52.0

ICD-10 code description

Acute pain

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

The intensity of the pain

Timepoint

3 minutes before and 3 minutes after Iv line

Method of measurement

OUCHER pain tools

Secondary outcomes**1****Description**

physiological parameters

Timepoint

3 minutes before and 3 minutes after the IV line
Method of measurement
Pulsoxymetry devices

Intervention groups

1

Description

Intervention group: In the combined group (deep breathing and hypnosis), the pain intensity and physiological indices are measured 3 minutes before the insertion and recorded in the questionnaire. One minute before the trampling, it is done by a deep tail with a nose and will die in the exhalation of the gingival, and after the death of the gig, the numbers will count up to 10 spins and 10 breaths. After 3 minutes, pain intensity and physiological indices are measured and recorded in the questionnaire. The tracking will be done before the end of counting the numbers

Category

Prevention

2

Description

Intervention group: In the deep breathing group, the pain intensity and physiological indices were measured 3 minutes before the insertion and recorded in the questionnaire. One minute before the pregnancy, a deep tail with a nose is done and the mouth is exhausted, and after each breath, the numbers will count up to 10 breaths. After 3 minutes, pain intensity and physiological indices are measured and recorded in the questionnaire. The tracking will be done before the end of counting the numbers.

Category

Prevention

3

Description

Intervention group: In the gig group, the pain intensity and physiological indices were measured 3 minutes before the insertion and recorded in the questionnaire. A minute before the tuneup, the gig will die, and after the death of the gig, numbers will count up to 10 rotations. After 3 minutes, pain intensity and physiological indices are measured and recorded in the questionnaire. The tracking will be done before the end of counting the numbers.

Category

Prevention

4

Description

Control group: Control group: The pain intensity and physiological indices were measured 3 minutes before the insertion and recorded in the questionnaire. The insertion is done and the measurement of pain intensity and physiological parameters is recorded 3 minutes after the insertion and recorded in the questionnaire.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Hosein Hospital

Full name of responsible person

Horiyeh Abdolalizadeh

Street address

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Postal code

-

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Email

hoabdolalizadeh@gmail.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mohammadreza Rashidi

Street address

Daneshgah Ave.

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Tabriz

Province

East Azarbaijan

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5138947977

Phone

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Email

mrashidi@gmail.com

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**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Horiyeh Abdolalizadeh

Position

Expert Nursing

Latest degree

Bachelor

Other areas of specialty/work

Pediatrics

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

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Full name of responsible person

Horiyeh Abdolalizadeh

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Other areas of specialty/work

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Individual characteristics of the samples (age, sex, grade of birth, degree of education, parents' education and literacy, place of residence, hospitalization history, number of family members, location of the venue, frequency and economic status), and the form of registration of pain after ineligible Identifying people to be shared.

When the data will become available and for how long

Start the access period, 6 months after printing the results

To whom data/document is available

Data will be available to researchers working in

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Arshadi Bostanabad

Position

PHD in Nursing

Latest degree

Ph.D.

Other areas of specialty/work

Pediatrics

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academic and academic institutions

Under which criteria data/document could be used

Use of the data provided for performing statistical analyzes is permitted

From where data/document is obtainable

Contact us at hoabdolalizadeh@gmail.com to receive the data.

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

After receiving the email from the email address listed, the data will be sent after 24 hours.

Comments

I have no other explanation.