

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Comparison of the effect of virtual reality and animation on pain control due to injections in children 3 to 6 years old.

Protocol summary

Study aim

Comparison of the effect of virtual reality and animation on pain control due to injections in children 3 to 6 years old.

Design

The clinical trial consisted of two intervention groups, one control group, single-blind and randomized on 135 children 3 to 6 years old. Children are assigned to groups based on a randomization sequence and first in first out that will be generated in advance, which is unpredictable and has no certain pattern. To assign samples to 3 groups, the block randomization method with the size of 3 and 6 blocks using block random number generator software will be used. All this will be done with software called Sealed Envelope.

Settings and conduct

This study will be performed in health centers of Arak city. A demographic information questionnaire will be collected through interviews. The child is filmed during the procedure and the pain level is measured using the Wong-Baker Faces pain rating scale. Eventually, data analysis is performed using SPSS 20 program. Only data analyzers will not know how the samples are placed in the groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Children 3 to 6 years old without underlying disease and lack of vision and hearing problems. Exclusion criteria: Child parents' unwillingness to participate in the study.

Intervention groups

First intervention group: In this group, from the beginning of the injection procedure to the end of the procedure, we use the virtual reality technique using 3D glasses to view Sponge Bob animation. Second intervention group: In this group, using a mobile phone, from before the injection procedure to its end, the Sponge Bob animation is displayed. Control group: In this group there is no intervention, only the injection will be performed.

Main outcome variables

Intensity of pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210501051142N1**

Registration date: **2021-09-08, 1400/06/17**

Registration timing: **prospective**

Last update: **2021-09-08, 1400/06/17**

Update count: **0**

Registration date

2021-09-08, 1400/06/17

Registrant information

Name

Aida Arjloo

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3402 0115

Email address

golmehrsherafati@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-16, 1400/06/25

Expected recruitment end date

2022-01-15, 1400/10/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the effect of virtual reality and animation on pain control due to injections in children 3 to 6 years old.

Public title
"The effect of virtual reality and animation on pain control due to injections "

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
No underlying disease in the child. Child parents' willingness to participate in the study.
Exclusion criteria:
Existence of vision and hearing problems in the child.

Age
From **3 years** old to **6 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **135**

Randomization (investigator's opinion)
Randomized

Randomization description
Children are assigned to two intervention groups and one control group based on the randomization sequence that will be generated in advance, which is unpredictable and its arrangement is completely random. To allocate the samples, the block randomization method with the size of 3 and 6 blocks will be used, so that by using the software for generating random numbers in the block method, a randomization sequence will be generated according to the sample size required for the three groups. First, all the modes in which the 3 letters A, B and C can be put together in blocks of 3 and 6 are generated, then a block is randomly selected by placing it among the blocks and the layout pattern in that block will be used to allocate children. Finally this block will be placed in the main container and another block will be selected again. Blocks of 3 and 6 will all be in the same container. All this will be done with software called Sealed Envelope. With this method, concealment will also be observed. The concept of concealment is to unpredictably assign individuals to groups that the researcher will not be able to predict which group the next person will be in.

Blinding (investigator's opinion)
Single blinded

Blinding description
The data analyzer will not know how the samples are placed in the intervention and control groups. Other people in the study will be aware of this placement.

Placebo
Not used

Assignment
Parallel

Other design features
-

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak university of medical sciences

Street address

Arak university of medical sciences, Basij Sq., Sardasht region

City

Arak

Province

Markazi

Postal code

3848176593

Approval date

2021-07-25, 1400/05/03

Ethics committee reference number

IR.ARAKMU.REC.1400.076

Health conditions studied

1

Description of health condition studied

pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Intensity of pain

Timepoint

During intervention

Method of measurement

Pain is measured by the Wong-Bakar Faces pain rating scale.

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: In this group, from the beginning of the injection procedure to the end of the procedure, we use the virtual reality technique using 3D glasses to view Sponge Bob animation and during the procedure, the child is filmed for a more comprehensive examination.

Category

Other

2

Description

Second intervention group: In this group, using a mobile phone, from before the injection procedure to its end, the Sponge Bob animation is displayed. During the procedure, the child is filmed for a more comprehensive examination.

Category

Other

3

Description

Control group: In this group there is no intervention, only the injection will be performed and the child will be filmed during the injection procedure for a more comprehensive examination.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Health centers of Arak city

Full name of responsible person

Mahbobeh Sajadi

Street address

Basij Sq., Sardasht region, Arak university of medical sciences

City

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Province

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Postal code

3819693345

Phone

+98 86 3493 4634

Email

golmehrsherafati@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

DR Alireza Kamali

Street address

University complex of the Great prophet, Basij square, Sardasht.

City

Arak

Province

Markazi

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3819693345

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Email

golmehrsherafati@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Arak University of Medical Sciences

Proportion provided by this source

80

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

Arak University of Medical Sciences

Full name of responsible person

Mahbobeh Sajadi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

University complex of the Great prophet, Basij square, Sardasht.

City

Arak

Province

Markazi

Postal code

3819693345

Phone

009886341735057

Email

golmehrsherafati@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Mahbobeh Sajadi

Position

Associate professor

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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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

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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Only the part of the data related to the original outcome will be able to be shared.

When the data will become available and for how long

since the winter of 2022

To whom data/document is available

Researchers and students in this field

Under which criteria data/document could be used

In order to control pain in children when injecting

From where data/document is obtainable

Vice chancellor for education and research, Arak university of medical sciences

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

These documents will be available on the website of Arak university of medical sciences.

Comments