

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

Investigating the effect of the magic glove technique on the pain and anxiety of children during Leupromer injection

Protocol summary

Study aim

Investigating the effect of the magic glove technique on the pain and anxiety of children during Leupromer injection

Design

A clinical trial with a control and intervention group, with parallel groups, examining the results in 60 children, blinding is not done, the block randomization method will be used. Available sampling and random allocation using the quadruple block method (through the randomization site)

Settings and conduct

The samples are randomly distributed into two control and intervention groups. Data collection is done before and after the injection. In the intervention group, the magic glove is performed and then the injection is performed, but in the control group without intervention, only the injection is performed.

Participants/Inclusion and exclusion criteria

Entry requirements: have mental health and alertness, be healthy in terms of hearing, have no pain due to illness, have experience with lopromer injection (1 or more injections have been done for them). Conditions of non-entry: receipt of sedative, painkiller or anti-anxiety medication, any life-threatening emergency, a score greater than 5 in reducing the child's pain in the desensitization stage of the magic glove technique

Intervention groups

In the intervention group, the magic glove technique will be performed before the injection of lopromer, but in the control group, only drug injection will be performed. Before the intervention, demographic information and anxiety measurement will be done in both groups, and after the injection, pain and anxiety measurement and comparison will be done in both groups.

Main outcome variables

Pain and anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240111060681N1**

Registration date: **2024-01-22, 1402/11/02**

Registration timing: **prospective**

Last update: **2024-01-22, 1402/11/02**

Update count: **0**

Registration date

2024-01-22, 1402/11/02

Registrant information

Name

Faezeh Rostamian

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-20, 1402/12/01

Expected recruitment end date

2024-08-21, 1403/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of the magic glove technique on the pain and anxiety of children during Leupromer injection

Public title
Investigating the effect of the magic glove technique on the pain and anxiety of children during Leupromer injection

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Having mental health and alertness Being healthy in terms of hearing No pain caused by the disease Have the experience of Leupromer injection (1 or more injections have been done for them). Boys and girls 3-12 years old
Exclusion criteria:
Receiving a sedative, pain reliever or anti-anxiety medication Any life-threatening emergency A score greater than 5 in reducing the child's pain in the desensitization stage of the magic glove technique

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: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
To assign the target group to one of the two study groups; The intervention group and the control group (group A and group B) will use the block randomization method with blocks of four. Then, the participants will be assigned to one of the two groups 1: magic glove, 2: no intervention according to the block randomization protocol (produced by Random Allocation Software) with a ratio of 1:1, In such a way, the researcher cannot predict which group of intervention the next person will be placed in. In order to hide the random allocation, the codes created by the software will be placed in opaque envelopes.

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 Committees of School of Nursing and Midwifery & Rehabilitation - Tehran University o

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Tehran University of Medical Sciences Central Building, intersection of Qods St.,Keshavarz Boulevard

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Approval date

2023-12-16, 1402/09/25

Ethics committee reference number

IR.TUMS.FNM.REC.1402.181

Health conditions studied

1

Description of health condition studied

anxiety

ICD-10 code

F93.1

ICD-10 code description

Phobic anxiety disorder of childhood

2

Description of health condition studied

pain

ICD-10 code

R52.0

ICD-10 code description

Acute pain

Primary outcomes

1

Description

Child anxiety

Timepoint

Before the start of the intervention and after the end of the injection.

Method of measurement

A revised anxiety behavioral observational instrument

2

Description

Child's pain

Timepoint

After the end of the injection

Method of measurement

Wong Baker Tool

Secondary outcomes

empty

Intervention groups

1

Description

.According to the Rel@x manual published by Aramideh et al., the magic glove technique consists of 4 steps. Step 1: Introducing the magic glove to the child "I have a magic glove to protect your arm well. Do you agree that Shall I explain to you why it is magical?" The nurse explains to the patient that the magic glove will help him change the sensations in his arm. It's important to avoid saying, "You won't feel any pain," as negative suggestions can lead to stress. Then, the nurse asks the patient to put his hand or arm in hers and suggests, "Relax in my hand." By feeling the full weight of the arm in his hand, the nurse makes sure that the patient has released his arm. The second step (applying the magic glove): The nurse asks the patient: "What kind of magic glove would you like to have? Can you Describe it to me?" He allows the patient's creativity to do this imaginative work. Then, the nurse pretends to take the magic glove described by the patient out of her pocket and place it on the patient's hand. He starts with the patient's fingers and then uses the palm of his other hand to gently stroke them up to the wrist or cubital area. The nurse ensures that the end of the glove is clearly marked with each stroke and for each finger. She performs these strokes several times while continuously talking to the child so that the patient can imagine the glove on his arm. Third stage (Desensitization): The nurse confirms the patient's sensory attention by talking about the process while putting on the magic glove. he does. "This glove protects you so you're aware of what's going on. It won't hurt you. While you're wearing the glove, you'll feel changes happening. Your arm is protected, it feels like you're going to be well protected from anything... Do you feel how protected your hand is?" The nurse repeats the same words over and over while applying the magic glove. At the end of the last stroke, the nurse gently squeezes the upper arm and says, "Here, the magic glove is in place. Now that you have your magic glove, you'll find that you won't be bothered anymore. It is going very well. It will be convenient." In this case, the nurse tests the glove to see how well this technique protects the patient. First, the nurse presses the back of the hand untouched by the magic glove 3 times with a sharp pencil and says : "This is a perfect sensation because there is no magic glove, so the score is 10 out of 10." He tests the hand with the magic glove by applying equal pressure. He asks the patient to rate the sensation out of 10. Score 5 or less is great. Now that the magic glove is in place, the nurse can administer the injection. Here, if necessary, the nurse adds another focus by asking the patient to talk about the magic glove and describe it. During the injection, he reminds the patient: "Notice how this glove protects you!" He continues to stroke the arm to adjust the glove if necessary. The fourth stage (end of treatment): After

the injection, the nurse removes the magic glove. He does this by stroking the arm in the opposite direction to make sure full sensation has returned to the patient's hand. He asks the patient to rub his hands as if he were washing them to normalize his feelings. This should be continued until the patient confirms that sensation has returned

Category

Behavior

2

Description

Control group: Without intervention, only injection is done.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir al-Momenin Hospital, Semnan city

Full name of responsible person

Sati Nickdarzi

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Sponsors / Funding sources

1

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research Assistant, Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Faezeh Rostamian

Position

Master Students in Pediatric Nursing, School of Nursing & Midwifery, Tehran University of Medical Sc

Latest degree

Bachelor

Other areas of specialty/work

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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