

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Comparison of the efficacy of EMLA anesthetic cream , 2% lidocaine gel and ice bag on the severity of pain caused by venipuncture in 6-12 hospitalized children Department of Pediatrics, Alhadi Shoushtar Hospital in 2018

Protocol summary

Study aim

Determination of the effect of EMLA anesthetic cream, 2% lidocaine gel and ice bag on severity of pain caused by angioedema in 6-12 years old children admitted to the pediatric ward of al-Hadi hospital in 2018

Design

This is a clinical study. The population studied in this study is children 12-6 admitted to the children's ward of Khatam al-Nabiya Hospital in Shoushtar city in 2018. 160 children were randomly selected using randomly selected random access criteria and blocks were randomly selected using four blocks, so that the block of 2 people will be placed in each intervention group. And will be divided into 4 groups of 40 people. The first group (using spelling anesthetic cream), the second group (using lidocaine gel 2%), the third group (using the ice bag) and the fourth group (control).

Settings and conduct

Khatam Al Anbia Hospital in Shoushtar

Participants/Inclusion and exclusion criteria

The criteria for entering the study included (alertness of the child, lack of urgent need for placenta, first incubation, lack of susceptibility to spelling cream (lidocaine and perilocaine), and absence of any skin disease. Exit criteria also included children who had Constipated, have taken a sedative with an effective medication, or have verbal, mental, vision, hearing and mental disorders.

Intervention groups

Includes 4 groups of 40 people: the first group (using spelling anesthetic cream), the second group (using lidocaine gel 2%), the third group (using the ice bag) and the fourth group (control).

Main outcome variables

Studying the pain of children during sedation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20121229011923N5**

Registration date: **2019-01-23, 1397/11/03**

Registration timing: **registered_while_recruiting**

Last update: **2019-01-23, 1397/11/03**

Update count: **0**

Registration date

2019-01-23, 1397/11/03

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-22, 1397/10/01

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of EMLA anesthetic cream , 2% lidocaine gel and ice bag on the severity of pain caused by venipuncture in 6-12 hospitalized children Department of Pediatrics, Alhadi Shoushtar Hospital in 2018

Public title

Comparison of the efficacy of EMLA anesthetic cream , 2% lidocaine gel and ice bag on the severity of pain caused by venipuncture in 6-12 hospitalized children Department of Pediatrics, Alhadi Shoushtar Hospital in 2018

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Being alert to the child Not having an urgent need to get pregnant Lack of susceptibility to spelling cream (lidocaine and perlocaine) The absence of any skin disease

Exclusion criteria:

Children who have already been pregnant Have taken a sedative or pain medication Have verbal, mental, vision, hearing and mental disorders.

Age

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

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **160**

Randomization (investigator's opinion)

Randomized

Randomization description

160 children were randomly selected using randomly selected random access criteria and blocks were randomly selected using four blocks, so that the block of 2 people will be placed in each intervention group. And will be divided into 4 groups of 40 people. The first group (using spelling anesthetic cream), the second group (using lidocaine gel 2%), the third group (using the ice bag) and the fourth group (control).

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**

Ethics Committee of Ahvaz Jundishapur University

Street address

Golestan Avenue, Esfand Alley

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Postal code

15794- 61357

Approval date

2018-11-17, 1397/08/26

Ethics committee reference number

IR.AJUMS.REC.1397.618

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

Evaluation of pain in children during sedation

ICD-10 code

R52

ICD-10 code description

Pain, unspecified

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

Evaluation of pain in children during IV line with Angiocate

Timepoint

Sampling will take place within 3 months

Method of measurement

In order to determine the severity of pain, a numerical scale of pain (NAS) and a behavioral pain scale (FLACC) will be used. The range of Numerical Scale (NAS) is from 0 to 10, where zero indicates no pain and a score of 5 indicates moderate pain and 10 indicates the highest pain rate. After explaining about the scoring and 5 minutes after the abdomen, the child is asked to measure his pain according to the numerical scale of the pain. Another tool is the use of the Behavioral Scale of Pain (FLACC), which includes five criteria for child behavior such as facial expression, foot movements, activity level, crying and relief, which is well known by nurses who are fully aware of the pain instrument. The behavior of the child is scored during the injection of this questionnaire. So the zero score for the least pain and the two score for the most pain in each criterion is considered. The score of each section is inserted separately and then the 5 sections are combined together to calculate the total pain behavior. The zero score range is the lowest and the 10 most range of these scores.

Secondary outcomes

empty

Intervention groups

1

Description

"Intervention group 1": Use of EMLA cream, spray cream 1.5 grams at the patient's placement site, 60-45 minutes before placement, and covered with semi-permeable dressing. After 45 minutes, the dressing is removed. And the cream with cotton alcohol will be cleaned up to 70%, and the nurse will work. "Intervention group 2": Using an ice bag, 5 pieces of ice with dimensions of 4 × 2 × 2 cm are placed in latex gloves and placed for 3 minutes on the spot, then remove the ice bag and place With alcohol cotton, 70% is cleaned and done by the nurse. "Intervention group 3": Use 2% lidocaine gel for 5 minutes for 12 minutes in the lidocaine gel vein and apply a semi-permeable dressing. Then, with cotton alcohol, remove the 70% gel. The nurse will go through. "control group" will be routine care.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Khatam Al Anbia Hospital in Shoushtar

Full name of responsible person

Shahnaz Rostami

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Akram Hemmatipour

Position

Nurse

Latest degree

Master

Other areas of specialty/work

Nursery

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

Yes - There is 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

Title and more details about the data/document

I do not know

When the data will become available and for how long

I do not know

To whom data/document is available

I do not know

Under which criteria data/document could be used

I do not know

From where data/document is obtainable

I do not know

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

I do not know

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

Ahvaz University of Medical Sciences

Full name of responsible person

Akram Hemmatipour

Position

Nurse

Latest degree

Master

Other areas of specialty/work

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