Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Nov 2026

Comparison of the effect of EMLA and massage on the pain and anxiety caused by intravenous insertion in hospitalized children of 3-6 years old

Protocol summary

Study aim
Determination and comparison of the effect of EMLA and massage on the control of pain and anxiety caused by intravenous insertion in children 3-6 years old

Design
four groups of 35 people. Three groups of intervention including massage, EMLA and EMLA with massage, a control group, a total sample size of 140 hospitalized children in the surgical ward, random allocation, parallel groups, lack of blinding

Settings and conduct
The researcher referred to Tabriz Pediatric Surgery Unit in the morning and identified the candidates for intravenous insertion and eligibility to enter the study. After obtaining consent and registering the demographic characteristics, random allocation was performed. At the evening shift, interventions were performed as described, and the data were recorded.

Participants/Inclusion and exclusion criteria
Inclusion criteria Age of 6 to 3 years having no pain before the start of venipuncture, having complete consciousness and physiological stability, lack of mental retardation lack of analgesic , sedative, corticosteroid and relaxant medication. Exclusion criteria The occurrence of any phenomenon violates the inclusion criteria to the study Failure to insert the intravenous line with one time cannula insertion

Intervention groups
In the EMLA group, one and half grams of EMLA cream was fixed, using the dressing, on the venipuncture site and after 60 minutes insertion was done. For the massage group, massage was carried out using a palpable motion in the palm of the hand on the around the venipuncture site, 5-minute before and during the insertion. In the third group, the EMLA and massage pairs were used. The control group, the insertion was done according to the units routine.

Main outcome variables
Pain: Behavioral and physiological responses Behavioral symptom of Anxiety

General information

Reason for update

Acronym
EMLA

IRCT registration information
IRCT registration number: **IRCT20190201042579N1**
Registration date: **2019-03-28, 1398/01/08**
Registration timing: **retrospective**

Last update: **2019-03-28, 1398/01/08**
Update count: **0**

Registration date
2019-03-28, 1398/01/08

Registrant information

Name
hanieh neshat

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 41 3477 7283

Email address
haie.neshat@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2016-08-23, 1395/06/02

Expected recruitment end date
2017-09-06, 1396/06/15

Actual recruitment start date
2016-08-23, 1395/06/02

Actual recruitment end date
2017-09-06, 1396/06/15

Trial completion date
2017-09-06, 1396/06/15

Scientific title
Comparison of the effect of EMLA and massage on the pain and anxiety caused by intravenous insertion in hospitalized children of 3-6 years old

Public title
The effect of EMLA and massage on the pain and anxiety of children

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Age of 6 to 3 years, having no pain before the start of venipuncture, having complete consciousness and physiological stability, lack of mental retardation lack of analgesic , sedative, corticosteroid and relaxant medication.

Exclusion criteria:
The occurrence of any phenomenon violates the inclusion criteria to the study Failure to insert the intravenous line with an cannula insertion into the skin and the need for re-effort,

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

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **140**
Actual sample size reached: **140**

Randomization (investigator's opinion)
Randomized

Randomization description
In order to sampling one of the colleagues was asked to select one of the two sealed envelopes, open it and inform the content. one of which was written odd days and in another even days. The selected envelope contained even days, and thus the children who were admitted to even days and had inclusion criteria were enrolled in the study.Then the children entered into the study through random selection One of the envelopes with the name of the groups was assigned to one of the four groups of control, massage, spelling, and spelling massage.available sampling

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 Tabriz University of Medical Sciences

Street address
Research Vice-Chancellor, Central Building No. 2, Third Floor, Tabriz University of Medical Sciences, Golgasht Street

City
Tabriz

Province
East Azarbaijan

Postal code
5166616471

Approval date
2016-05-09, 1395/02/20

Ethics committee reference number
IR.TBZMED.REC.1395-134

Health conditions studied

1

Description of health condition studied
Children who needed surgery and intravenus line insertion to repair stenosis in the esophagus.

ICD-10 code
K22.2

ICD-10 code description
Esophageal obstruction

2

Description of health condition studied
Children with inguinal hernia who needed surgery did not have pain during the procedure

ICD-10 code
K40

ICD-10 code description
Inguinal hernia

3

Description of health condition studied
Children with inguinal hernia who needed surgery and did not have pain during the procedure

ICD-10 code
K42

ICD-10 code description
Umbilical hernia

4

Description of health condition studied
Children who needed intravenus cannula insertion for surgery to remove Obstruction of gallbladder.

ICD-10 code
K82.0

ICD-10 code description
Obstruction of gallbladder

Primary outcomes

1

Description
behavioral changes related to Pain
Timepoint
behavioral changes related to Pain were evaluated Immediately after the cannula insertion of the skin
Method of measurement
behavioral changes related to pain with the wong baker face and FLACC Pain Rating Scale

2

Description
changes of the amount of anxiety
Timepoint
Before and After of Intravenus Line Insertion
Method of measurement
visual anxiety scale

3

Description
changes in heart rate related to pain
Timepoint
measurement of heart rate before and immediately after cannula insertion
Method of measurement
heart rate were measured with calibrate pulse oximetry that its model is novametrix.

4

Description
changes in arterial oxygen saturation percentage related to pain
Timepoint
measurement of arterial oxygen saturation percentage before and immediately after cannula insertion
Method of measurement
arterial oxygen saturation percentage were measured with calibrate pulse oximetry that its model is novametrix.

5

Description
changes in respiratory rate related to pain.
Timepoint
measurement of respiratory rate before and immediately after cannula insertion
Method of measurement
Respiratory rate were measured by counting in a one minute by nurse.

6

Description
changes in blood pressure related to pain.
Timepoint
measurement of blood pressure before and immediately after cannula insertion
Method of measurement
blood pressure were measured by the calibrate mercury barometer appropriate to the child's arm size (Model: fmt).

Secondary outcomes

empty

Intervention groups

1

Description
First Intervention group: First intervention group: EMLA cream 1.5 grams of EMLA cream 5%(One gram containing 25 mg of lidocaine and 25 mg of perlocaine) was used, which was done 60 minutes before injection at the injection site using a dressing and after 60 minutes IV insertion was done
Category
Prevention

2

Description
Second Intervention group: Massage in the form of slow motion with a medium pressure of the palms on the skin of the hands and arms and slow-blows of the area of the insertion that was done from 5 minute before and during the insertion.
Category
Prevention

3

Description
Third Intervention group: EMLA cream and massage were used simultaneously as described.
Category
Prevention

4

Description
Control group: The intravenous line insertion procedure was performed according to the routine of ward.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Tabriz Children Hospital
Full name of responsible person
Mir Hadi Musavi

Street address
Tabriz Children Hospital, Sheshgelan Street
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East Azarbaijan
Postal code
5136735886
Phone
+98 41 3526 2250
Email
kodakanhospital@tbzmed.ac.ir
Web page address
https://childrenhospital.tbzmed.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Pediatric Health Research Center
Street address
Pediatric Health Research Center, Tabriz Children Hospital, Sheshgelan Street
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Fax
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Email
Phrc_mb@tbzmed.ac.ir
Web page address
https://phrc.tbzmed.ac.ir
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
Hanieh Neshat
Position
PhD student in nursing
Latest degree
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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
Yes - There is a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Participants' age and weight, gender, scales pain scores, physiological indicators scores and anxiety scores by groups
When the data will become available and for how long
Start access from publication of results
To whom data/document is available
For researchers, educators, students and health professionals
Under which criteria data/document could be used
For further research and for use in the clinic
From where data/document is obtainable
By contacting the author of the email hanie.neshat@gmail.com
What processes are involved for a request to access data/document
The applicant can access them after their complete introduction and explanation of the reason for applying and how to use the data.
Comments