Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the Effect of EMLA Cream on Intravenous Cannulation Pain of 2-6 years Old Children : Comparison of Application between 20 and 60 Minutes before Cannulation with control group.

Protocol summary

Summary

The purpose of the study:Comparison of the Effect of EMLA Cream on Intravenous Cannulation Pain of 2-6 years Old Children : Comparison of Application between 20 and 60 Minutes before Cannulation. Study Design:Double-blind randomized clinical trial The inclusion criteria : children 6-2 years old admitted for elective small surgery ,who are conscious and calm or be able to calm down with the usual ways . The exclusion criteria : restless children , the children with loss of consciousness , children receive sedative or analgesic and children with a history of sensitivity to lidocaine. Intervention: reduce close dressing time with EMLA cream (from 60 to 20 minutes) Time of intervention: before Intravenous Cannulation Primary outcome of study: savings in time and the possibility of using EMLA crem in emergency.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015051822309N1**
Registration date: **2015-12-11, 1394/09/20**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-12-11, 1394/09/20

Registrant information

Name

Behzad Aliakbari Sharabiani

Name of organization / entity

Tabriz University of Medical Sciences, Faculty of Medicine

Country

Iran (Islamic Republic of)

Phone

+98 41 3334 1994

Email address

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Recruitment status

Recruitment complete

Funding source

supplied by the researcher.

Expected recruitment start date

2015-04-09, 1394/01/20

Expected recruitment end date

2015-06-10, 1394/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effect of EMLA Cream on Intravenous Cannulation Pain of 2-6 years Old Children : Comparison of Application between 20 and 60 Minutes before Cannulation with control group.

Public title

Comparison of the Effect of EMLA Cream on Intravenous Cannulation Pain of 2-6 years Old Children : Comparison of Application between 20 and 60 Minutes before Cannulation.

Purpose

Treatment

Inclusion/Exclusion criteria

The inclusion criteria : children 6-2 years old admitted for elective small surgery ,who are conscious and calm or be able to calm down with the usual ways . The exclusion

criteria : restless children , the children with loss of consciousness , children receive sedative or analgesic and children with a history of sensitivity to lidocaine.

Age
From **1 year** old to **5 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **231**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tabriz University of Medical Sciences

Street address
Golgasht st., University of Medical Sciences,Faculty of Medicine

City
Tabriz

Postal code

Approval date
2015-01-12, 1393/10/22

Ethics committee reference number
93150

Health conditions studied

1

Description of health condition studied
Local Anesthesia

ICD-10 code
R20.0

ICD-10 code description
Anaesthesia of skin

Primary outcomes

1

Description
pain severity

Timepoint
20 and 60 minute after intervention

Method of measurement
based on FLACC Behaviorral Tool table

Secondary outcomes

1

Description
time to onset of drug action

Timepoint
20 and 60 minute

Method of measurement
with timer

Intervention groups

1

Description
Group 1: EMLA cream, with 2cm lenght and 0.5cm diameter (0.5 gr) in occlusive dressing, 20 minute before cannulation

Category
Treatment - Drugs

2

Description
Group 2: EMLA cream, with 2cm lenght and 0.5cm diameter (0.5 gr) in occlusive dressing, 60 minute before cannulation.

Category
Treatment - Drugs

3

Description
Group 3(control):Vitamin A+D cream, with 2cm lenght and 0.5cm diameter in occlusive dressing,60 minute before cannulation.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Tabriz Children Hospital

Full name of responsible person
Behzad Aliakbari Sharabiani

Street address
Sheshgilan street

City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
We do not have financial support
Full name of responsible person
Behzad Aliakbari Sharabiani
Street address
OR, Pediatric Hospital, Sheshgilan street, Tabriz
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
We do not have financial support
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
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Full name of responsible person
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Web page address
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty