

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 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 cream 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

aliakbarib@tbzmed.ac.ir

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

Tabriz Medical University -Faculty of Medicine

Full name of responsible person

Hossein Razmi Dizaj

Position

Medical Student

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

University of medicine - Faculty of Medicine

Full name of responsible person

Behzad Aliakbari Sharabiani

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Person responsible for updating data

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University of Medicine - Faculty of Medicine

Full name of responsible person

Hossein Razmi Dizaj

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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