

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect of Vapocoolant spray and EMLA cream in reduction of pain and anxiety caused by venipuncture in 6-12 years old children with Thalassemia in Tehran thalassemia center

Protocol summary

Summary

The aim of current study is to compare the effect of Vapocoolant spray and lidocaine/procaine cream in reduction of pain and anxiety caused by venipuncture in 6-12 years old children with Thalassemia. The main inclusion criteria is the need of frequent blood transfusion. The main exclusion criteria is acute complications like vapocoolant spray or lidocaine or procaine during the study. The study population is children with thalassemia referring to hematology clinic of Ali-Asghar hospital, in Tehran. In this study, 40 eligible children with convenience sampling method are enrolled and allocated in two groups with blocking design. First in both groups, the catheterization is done without any intervention, then in group one, initially used from EMLA Cream and then Vapocoolant Spray and the opposite action will be done in the second group. After each intervention the patient's pain and anxiety are measured. Pain and anxiety measurement will be done in three phases: without intervention(control), after lidocaine/procaine cream and after Vapocoolant Spray application.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015062222815N2**
Registration date: **2015-11-19, 1394/08/28**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-11-19, 1394/08/28

Registrant information

Name

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Name of organization / entity

University of social welfare and rehabilitation sciences

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Recruitment status

Recruitment complete

Funding source

University of Social Welfare and Rehabilitation Sciences

Expected recruitment start date

2015-07-06, 1394/04/15

Expected recruitment end date

2015-09-06, 1394/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Vapocoolant spray and EMLA cream in reduction of pain and anxiety caused by venipuncture in 6-12 years old children with Thalassemia in Tehran thalassemia center

Public title

The comparission of EMLA cream and vapocoolant spray in reducing pain and anxiety in catheterization

Purpose

Other

Inclusion/Exclusion criteria

Inclusion Criteria: 6-12 years old children with major

thalassemia registered in thalassemia center; Full consciousness and fluency the Persian language to communicate appropriately and the ability to communicate verbally; Not using analgesics and anti anxiety agents Exclusion Criteria: Any acute side effects related to the interventions

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

University of Social Welfare and Rehabilitation Sciences

Street address

Kodakyar Ave, Daneshjo Blvd, Evin

City

Tehran

Postal code

1985713834

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

USWR.REC.1393.233

Health conditions studied

1

Description of health condition studied

Pain during Venupuncture

ICD-10 code

Y60.6

ICD-10 code description

During aspiration, puncture and other catheterization

Primary outcomes

1

Description

Pain

Timepoint

In three phases: without intervention, after EMLA Cream and after Vapocoolant Spray application

Method of measurement

Visuale analoge Scale

Secondary outcomes

1

Description

Anxiety

Timepoint

In three phases: without intervention, after EMLA Cream and after Vapocoolant Spray application

Method of measurement

Visuale analoge Scale for Anxiety

Intervention groups

1

Description

First in group one, the catheterization is done without any intervention, then before second catheterization used from EMLA Cream and then Vapocoolant Spray

Category

Treatment - Other

2

Description

First in group two, the catheterization is done without any intervention, then before second catheterization used from Vapocoolant Spray and then EMLA Cream.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali-Asghar Children Hospital

Full name of responsible person

Educational Supervisor of Ali-Asghar Children Hospital

Street address

Zafar St, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of Social Welfare and Rehabilitation Sciences

Full name of responsible person

Asghar Dalvandi

Street address

Kodakyar Ave, Daneshjo Blvd, Evin

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

University of Social Welfare and Rehabilitation Sciences

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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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