

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effectiveness of Xyla-p and cold needle cream on fear and pain during venipuncture in children under chemotherapy

Protocol summary

Study aim

Comparison of the effectiveness of Xyla-p and cold needle cream on pain intensity during venipuncture in children under chemotherapy

Design

This double-blind, parallel-group randomized controlled trial included 87 children aged 2–6 years undergoing outpatient chemotherapy in Mashhad, Iran. Participants were randomized into four groups: control (routine care), cold angiocath, Xylap cream, and combination. Pain intensity and fear were assessed using the Face, Legs, Activity, Cry, Consolability (FLACC) and Children's Fear Scale (CFS), respectively, across four venipuncture sessions (one baseline, three intervention).

Settings and conduct

Sampling will be done in the chemotherapy ward of Sheikh Mashhad Hospital for children with leukemia aged 2–6 years. Children and statistical analysts do not know how to inject.

Participants/Inclusion and exclusion criteria

Inclusion criteria Age of 6 to 2 years, having complete consciousness, sedative medication and Receive chemotherapy every week At least one month has passed since the onset of the disease. the exclusion criteria to the study: Failure to insert the intravenous line with one time cannula insertion

Intervention groups

In the first week, as basic information is collected, the injection is performed routinely, without any cream or angiocatheter with a needle at room temperature. In the following weeks, injections will be performed 3 times in one of the 4 methods (The first group is xylophone and cold angiocatheter, the second group of angiocatheter with cold needle and moisturizing cream, the third group of xylophone cream and angiocatheter with room temperature, the fourth group of moisturizing cream and angiocatheter with needle at room temperature.). Therefore, intervention and data collection in each child is measured in 4 times.

Main outcome variables

Pain; Fear

General information

Reason for update

The fear variable was initially measured because it was considered a confounding variable to estimate the effect of this confounder on the study results. Then, it was decided that reporting this variable as a dependent variable could provide more information (the effect of independent variables on pain as well as fear) to the readers of the article.

Acronym

IRCT registration information

IRCT registration number: **IRCT20131113015393N7**

Registration date: **2021-11-06, 1400/08/15**

Registration timing: **prospective**

Last update: **2025-10-21, 1404/07/29**

Update count: **1**

Registration date

2021-11-06, 1400/08/15

Registrant information

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Narjes Heshmati Far

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-27, 1400/08/05

Expected recruitment end date

2022-07-27, 1401/05/05

Actual recruitment start date

2021-11-13, 1400/08/22

Actual recruitment end date

2023-02-26, 1401/12/07

Trial completion date

2023-02-26, 1401/12/07

Scientific title

Comparison of the effectiveness of Xyla-p and cold needle cream on fear and pain during venipuncture in children under chemotherapy

Public title

Comparison of the effectiveness of Xyla-p and cold needle cream on fear and pain

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Aged between 18 to 65 years Have leukemia Outpatients refer to the chemotherapy department Receive chemotherapy every week At least one month has passed since the onset of the disease

Exclusion criteria:

Restless children The children with loss of consciousness Children receive sedative or analgesic Children with a history of sensitivity to lidocaine.

Age

From **2 years** old to **6 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **87**

Actual sample size reached: **87**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was performed using a computer-generated random list with permuted blocks of size eight, prepared by an independent statistician. Allocation was concealed using 88 sequentially numbered, opaque, sealed envelopes, opened at the time of assignment.

Blinding (investigator's opinion)

Double blinded

Blinding description

This is a double-blind study. The participant (child and parent) is not aware of the injection method. The statistical analyzer will not know the injection method and the data will be provided to him in the form of codes A, B, C and D.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Sabzevar University of Medical Sciences

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Deputy of Research and Technology, Sabzevar University of Medical Sciences, SHohada Hastei Boulevard.

City

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Province

Razavi Khorasan

Postal code

9617913114

Approval date

2021-06-13, 1400/03/23

Ethics committee reference number

IR.MEDSAB.REC.1400.041

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

Acute pain

ICD-10 code

G89.1

ICD-10 code description

Acute pain, not elsewhere classified

2**Description of health condition studied**

Fear

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Pain

Timepoint

Before and during the intervention

Method of measurement

Flacc Scale

2

Description

Fear

Timepoint

Before and during the intervention

Method of measurement

Children's Fear Scale

Secondary outcomes

empty

Intervention groups

1

Description

In the present research, we will have 2 methods (2 intervention) for injection. The first method, using cold angiocatheter: venipuncture is performed by cooled angiocatheter kept at -20 °C freezer for at least one hour in a steel box. After identifying the target vein, the angiocatheter is immediate will be removed from the freezer and the venipuncture will be performed. The second method, using Xyla-p cream: venipuncture is done by rubbing 2.5 grams of Xyla-p cream on the 20-25 cm2 and covering it with nylon dressing for at least 45 minutes. This intervention of study will be conducted in 4 groups of participants. The maximum dose of the cream for a child, weighing more than 10 kg is 100 g of cream per 100 cm2 of the skin for 4 hours according to the available guidelines. Due to the dose used in this study, there is no possibility of complications such as skin allergies. Intervention group: The intervention in group 1 is that Xyla-p cream (first intervention) and cold angiocatheter (second intervention) are used.

Category

Treatment - Devices

2

Description

Intervention group 2: The intervention is performed using Xyla-p cream (first intervention) and angiocatheter at room temperature (routine method).

Category

Treatment - Devices

3

Description

Intervention group 3: This includes performing the intervention using moisturizing cream (placebo) and cold angiocatheter (intervention).

Category

Treatment - Devices

4

Description

Control group: In this group, moisturizing cream (placebo) and angiocatheter are used at room

temperature (routine method).

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Sheikh Hospital of Mashhad

Full name of responsible person

Fateme borzoe

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Sabzevar 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

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Person responsible for general inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Not applicable

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