Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

Name
Narjes Heshmati Far
Name of organization / entity
Sabzevar University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 57 1444 6070
Email address
nheshmatifar@yahoo.com

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
Street address
Deputy of Research and Technology, Sabzevar University of Medical Sciences, SHohada Hastei Boulevard.
City
Sabzevar
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 borzoee
Street address
Dr. Sheikh Hospital,Tohid Square, Motahari Avenue
City
Mashhad
Province
Razavi Khorasan
Postal code
9617913114
Phone
+98 51 4401 1000
Email
borzoee75026@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
Alireza Javadinia
Street address
Shohadaye Hasteii Boulevard
City
Sabzevar
Province
Razavi Khorasan
Postal code
9617913112
Phone
+98 51 4401 1000
Email
javadinia@gmail.com
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

Person responsible for general inquiries

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Fateme Borzoee

Position

Faculty member of Sabzevar University

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

School of Nursing and Midwifery; Shohadaye Hasteii Boulevard, Sabzevar

City

sabzevar

Province

Razavi Khorasan

Postal code

9617913112

Phone

+98 51 4401 1000

Email

borzoee75026@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Fateme Borzoee

Position

Faculty member of Sabzevar University

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

School of Nursing and Midwifery; Shohadaye Hasteii Boulevard, Sabzevar

City

sabzevar

Province

Razavi Khorasan

Postal code

9617913112

Phone

+98 51 4401 1000

Email

borzoee75026@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Fateme Borzoee

Position

Faculty member of Sabzevar University

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

School of Nursing and Midwifery; Shohadaye Hasteii Boulevard, Sabzevar

City

sabzevar

Province

Razavi Khorasan

Postal code

9617913112

Phone

+98 51 4401 1000

Email

borzoee75026@yahoo.com

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