

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Comparison of the effect of acetaminophen syrup with oral ibuprofen in reducing pain caused by peripheral vascularization in children with acute lymphoblastic leukemia.

Protocol summary

Study aim

Comparison of the effect of acetaminophen syrup with oral ibuprofen in reducing pain caused by peripheral vascularization in children with acute lymphoblastic leukemia.

Design

A clinical trial with a control group with parallel and double-blind randomized phase 2 of 90 patients with a randomization method using the rand function of Excel software.

Settings and conduct

This Double Blind (in Patient and Caretaker) study will be done in Hematology & Oncology ward in Bu-Ali-Sina Hospital in Sari, Mazandaran So that the drugs with the same volume and appearance reach the respected nurse without prior notice, and one hour after prescribing the drug, vein sampling is done by the same nurse and the results are recorded by her.

Participants/Inclusion and exclusion criteria

All children Diagnosed with ALL and Age between 3-12 years old are included patients with Allergic history of Acetaminophen or Ibuprofen patients with consumption of drugs which may have cross reactions with the given drugs patients with $plt < 50,000$ patient with Neutrophil count < 1500 patient with Fever or Nausea/ Vomiting

Intervention groups

First group with Acetaminophen Syrup , 15mg/kg Second group with Ibuprofen syrup , 10mg/kg Third group no interference and be giving Placebo with same Volume and Color

Main outcome variables

Pain reduction in patients and their families & progress in cure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190202042583N5**

Registration date: **2023-11-11, 1402/08/20**

Registration timing: **prospective**

Last update: **2023-11-11, 1402/08/20**

Update count: **0**

Registration date

2023-11-11, 1402/08/20

Registrant information

Name

Mohammad Naderisorki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3334 7837

Email address

dr.naderisorki@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-22, 1402/09/01

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of acetaminophen syrup with

oral ibuprofen in reducing pain caused by peripheral vascularization in children with acute lymphoblastic leukemia.

Public title

Comparing the effect of acetaminophen and ibuprofen in reducing the pain of venipuncture

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

All Children between 3-12 years old diagnosed with ALL came for Chemotherapy

Exclusion criteria:

People younger than 3 years old and older than 12 years old
Neutrophil < 1500
Allergic history of Acetaminophen/Ibuprofen
Plt<50,000
Fever & Nausea/ Vomiting
Hb < 8g/litre
Hepatic disfunction

Age

From **3 years** old to **12 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

We divide each client into two groups using a random table. This table is a set of numbers. Consider the numbers 1 to 19 for intervention A and the numbers 20 to 38 for control B (for both size groups larger and smaller than 4 cm). Then we touch one of the numbers and move into one of the predetermined directions and record the numbers and assign them to one of the groups. In this way, patients are divided completely randomly.

Blinding (investigator's opinion)

Double blinded

Blinding description

This Study is Double Blind and the patients and the care takers are unaware of the drugs type which have the same color, Volume and Tube. In addition, The psychiatrist observing the images is not aware of the type of medication received.

Placebo

Used

Assignment

Other

Other design features**Secondary Ids**

empty

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

Ethics committee of Mazandaran University of Medical Sciences

Street address

Mazandaran University of Medical Sciences, Se-rah-Joibar, Sari

City

Sari

Province

Mazandaran

Postal code

48157-33971

Approval date

2023-08-15, 1402/05/24

Ethics committee reference number

IR.MAZUMS.REC.1402.305

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

Acute lymphoblastic leukemia

ICD-10 code

C91.0

ICD-10 code description

Acute lymphoblastic leukemia [ALL]

Primary outcomes**1****Description**

Drug effects on pain reduction during IV needle insertion

Timepoint

Pain reduction of needle insertion 60 minutes after oral taking of drugs

Method of measurement

Ouches pain scale

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: prescription of acetaminophen syrup with 15mg/kg dosing, once, taken orally 1hour before needle insertion

Category

Treatment - Drugs

2

Description

Intervention group: prescription of Ibuprofen syrup with 10mg/kg dosing, once, taken orally 1hour before needle insertion

Category

Treatment - Drugs

3

Description

Control group: prescription of placebo with same amount as previous drugs once, taken orally 1hour before needle insertion

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Bu-Ali Sina Hospital

Full name of responsible person

Mohammad Naderisorki

Street address

Bu Ali Sina Hospital, Pasdaran Blvd, Sari, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Pedram Ebrahim Nejad

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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

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Mohammad Naderisorki

Position

Assistant Professor professor

Latest degree

Subspecialist

Other areas of specialty/work

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Latest degree

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Subspecialist

Other areas of specialty/work

Hematology

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Mazandaran

Postal code**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

Undecided - It is not yet known if there will be a plan to make this available

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