

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

Comparison of the effect of evaporative spray and music on pain of intravenous injection in children with thalassemia

Protocol summary

Study aim

Comparison of the effect of evaporative spray and music on pain of intravenous injection in children with thalassemia

Design

clinical trial with cross-over design

Settings and conduct

The study will be conducted at Pastour Hospital in Bam. Pain will be assessed before and after infusion in three consecutive visits for blood transfusion. In the first transfusion session, no interventions will be performed. In the second session evaporative spray will be used before venipuncture, and in the third session music will be used. The person assessing the pain will be unaware of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Children 6 to 12 years old with thalassemia; full level of consciousness ,Exclusion criteria: Inability to respond to pain assessment scales; use of pain relief during injection;

Intervention groups

The control group: The child is considered as control group at the first transfusion session and does not receive any intervention in this session. The Intervention Group 1: In the second transfusion session,the same child in the control group receives evaporative spray before the transfusion. The evaporative spray used in this study will be an ice spray made in Italy with the exclusive representation of Novin Medical Equipments Company. For all children, the catheter number 22 made by Debi, and 60% alcohol of Razi Company will be used. The Ice spray will be applied from 25 cm distance for 5 seconds. The Intervention Group 2: In the third transfusion session,the same child in the control group will listen to their chosen music before the transfusion. The music will be their choice that will be played through the headphones.The music will be played for 30 minutes during the day before the blood transfusion

Main outcome variables

Intravenous injection pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111019007844N13**

Registration date: **2020-03-13, 1398/12/23**

Registration timing: **registered_while_recruiting**

Last update: **2020-03-13, 1398/12/23**

Update count: **0**

Registration date

2020-03-13, 1398/12/23

Registrant information

Name

Mansour Arab

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 1320 5179

Email address

marab@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-20, 1398/09/29

Expected recruitment end date

2021-12-20, 1400/09/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of evaporative spray and music on pain of intravenous injection in children with thalassemia

Public title

Comparison of the effect of evaporative spray and music on pain

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Children 6 to 12 years old with thalassemia Full level of consciousness

Exclusion criteria:

Inability to respond to pain assessment scales Use of pain relief during injection Dissatisfaction with participation in the study

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

The outcome assessor is not aware of the pain relief method (music or spray) that was used.

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Bam University of Medical Sciences

Street address

Bam University of Medical Science., Shahid Rajaiee Blvd., Sardaran Shahid Square., Bam City

City

Bam

Province

Kerman

Postal code

7661712669

Approval date

2019-05-17, 1398/02/27

Ethics committee reference number

IR.MUBAM.REC.1398.037

Health conditions studied

1

Description of health condition studied

Intravenous injection pain

ICD-10 code

G89.1

ICD-10 code description

Acute pain, not elsewhere classified

Primary outcomes

1

Description

Pain of Intravenous Injection

Timepoint

Before and after the intervention

Method of measurement

FLACC Pain Scale (Face, Legs, Activity, Cry, Consolability Scale) and Numeric Rating Pain Scale

Secondary outcomes

empty

Intervention groups

1

Description

Control group: The child is considered as the control group at the first injection session. In the control group, no intervention is performed and a 22G intravenous catheter is inserted to the vein as usual by nurse.

Category

Other

2

Description

Intervention group 1: The same child in the control group received intervention in the second session of injection and received evaporative spray before injection.

Intervention 1: Ice spray product from Italy with the exclusive representation of Novin Medical Equipments Company (The chemical composition: Menthol, Isopropyl alcohol, Isopropyl myristate, Butane-propane gas & Essence), which is used once by the nurse at 25 cm distance for 5 seconds at the venipuncture site and then a 22G intravenous catheter is inserted to the vein.

Category

Other

3**Description**

Intervention group 2: The same child in the control group received intervention in the third injection session and listened to their choice music prior to injection.

Intervention: The child's chosen music from a list of ten kid songs is played through the headphones for 30 minutes prior to injection and then a 22G intravenous catheter is inserted to the vein by nurse.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Pastor Hospital, The Special Diseases Center

Full name of responsible person

Masomeh Ghasemi

Street address

Pastor Hospital., Persian Gulf Blvd., Bam-Baravat Road., Bam

City

Bam

Province

Kerman

Postal code

7661712669

Phone

+98 34 4421 9248

Email

dr.ghasemi43@yahoo.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Bam University of Medical Sciences

Full name of responsible person

Friba Borhani

Street address

Bam University of Medical Science., Shahid Rajaiee Blvd., Sardaran Shahid Square., Bam City

City

Bam

Province

Kerman

Postal code

7661713669

Phone

+98 34 4421 9248

Email

research.bam@mubam.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Bam 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**

Bam University of Medical Sciences

Full name of responsible person

Masomeh Ghasemi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

Street address

Bam University of Medical Science., Shahid Rajaiee Blvd., Sardaran Shahid Square., Bam City

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Bam

Province

Kerman

Postal code

7661713669

Phone

+98 34 4421 9248

Fax

+98 34 4421 9248

Email

dr.ghasemi43@yahoo.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Bam University of Medical Sciences

Full name of responsible person

Masomeh Ghasemi

Position

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Latest degree

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Person responsible for updating data

Contact

Name of organization / entity

Bam University of Medical Sciences

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The main outcome data will be shared.

When the data will become available and for how long

6 months after publishing the results

To whom data/document is available

Researchers

Under which criteria data/document could be used

There is no condition

From where data/document is obtainable

dr.ghasemi43@yahoo.com

What processes are involved for a request to access data/document

I will respond promptly by email request.

Comments