Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
City
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
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

City
Bam

Province
Kerman

Postal code
7661712669

Phone
+98 34 4421 9248

Email
dr.ghasemi43@yahoo.com

Person responsible for updating data

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

City
Bam

Province
Kerman

Postal code
7661713669

Phone
+98 34 4421 9248

Email
dr.ghasemi43@yahoo.com

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