Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Nov 2026

Comparing the efficiency of Hegu point massage with ice on severity of venipuncture pain compared to placebo in children with thalassemia referring to Kerman Samenolhojaj Medical Center in 2014

Protocol summary

Summary

This clinical trial study is of double-blind two-group type. The aim of this research is to study the effect of ice massage of Hegu point and placebo on severity of venipuncture pain. Inclusion criteria included “Thalassemic children aged 6-12 and patient’s willingness to participate in the study.” However, children with physical problems (verbal, mental, visual and auditory), medication to reduce pain for up to 8 hours prior to venipuncture, penetration of more than one catheter into the skin, prolonged duration of catheter insertion (over a minute). Statistical population includes children referring to Kerman Samenolhojaj Medical Center. 86 children were selected using stratified random sampling method; they were placed into two experimental (Hegu point massage with ice) and placebo (touching ice marble on fake point of back of the hand) groups. Data was collected using a questionairer about the child's demographic information and Flacc behavioral pain scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014060117941N1**
Registration date: **2014-07-19, 1393/04/28**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-07-19, 1393/04/28

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Kerman University of Medical Science

Expected recruitment start date

2014-07-01, 1393/04/10

Expected recruitment end date

2014-08-11, 1393/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the efficiency of Hegu point massage with ice on severity of venipuncture pain compared to placebo in children with thalassemia referring to Kerman Samenolhojaj Medical Center in 2014

Public title

Effect of hegu point massage with ice on intensity of pain due of venipuncture

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria: Thalassemic children aged 12-6; in a case of Thalassemia Center; alert to the location; time; person; verbal communication ability; willingness of the

patient to participate in the study Exclusion criteria: Children with physical problems (verbal, mental, visual and auditory); mental disorders; medications to reduce pain for up to 8 hours before venipuncture; enter more than one catheter to the skin; over a prolonged period of catheter insertion minute; Disorders diabetic neuropathy; fractures and inflammation in the massage; have any pain before venipuncture.

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

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **86**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Center, Kerman University of Medical Sciences

Street address
Crossroads Thmasabad, Kerman

City
Kerman

Postal code

Approval date
2014-06-30, 1393/04/09

Ethics committee reference number
93102

Health conditions studied

1

Description of health condition studied
pain

ICD-10 code
R52.9

ICD-10 code description
Pain, unspecified

Primary outcomes

1

Description
pain

Timepoint
Start of the study

Method of measurement
Flacc Behavioral Pain Scale.

Secondary outcomes

empty

Intervention groups

1

Description
In group experimental for determine the Hegou point, child's thumb was placed in the adduction position; in this case, a muscular prominence peak (related to the thumb adductor) was the Hegu point. then some icy marbles (2 cm in diameter) were placed in plastic gloves and then were wrapped into one-layer cotton cloth. The researcher messaged the subject’s hand (the hand that was not used for venipuncture) slowly and rotationally with icy marbles 5 minutes before penetrating IV (researcher was trained by an expert in this regard). Each time, maximum pressure was for one minute, and massage was stopped for 10 seconds. This intervention lasted for 5 minutes.

Category
Rehabilitation

2

Description
. In the placebo group, the same method was used except that the icy marbles were placed on the fake point on back of the hands without any pressure or massage (the area between the third and fourth metacarpal bones)

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Kerman Medical Center Samen Al hojaj.

Full name of responsible person
Mrs, Farah Bakhsh

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ST Khorshid, Kerman

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Science
Full name of responsible person
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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
Kerman University of Medical Science
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty