

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The effect of foot massage on pain severity due to intravenous catheter insertion in hospitalized preschool children at pediatric ward of Hamadan Besat Hospital 2019

Protocol summary

Study aim

The purpose of this study was to determine the effect of foot massage on intravenous infants admitted to pediatric ward

Design

Clinical trial with control group, without blinding, non-randomized

Settings and conduct

Study setting for pediatric wards of Besat hospital in Hamadan. The control group and the test group will be randomly selected in the first week of each group, after which the test and control groups will be sampled one by one. In the test group, foot massage will be performed for 5 minutes. The control group did not receive any intervention. Then venipuncture will be performed. The heart rate and arterial oxygen saturation percentage will be recorded immediately before the baby enters the room, during venipuncture, and two minutes after venipuncture. The pain assessment will be recorded by the researcher using the FLACC scale during venipuncture and two minutes after venipuncture.

Participants/Inclusion and exclusion criteria

Child hospitalized 3 to 6 years old; organ and skin health in the legs; no analgesic medication for 3 hours before venipuncture; a child's consciousness of place and time; lack of mental retardation; no respiratory problems; no congenital heart disease; first time hospitalized child; the second time venipuncture; no acute pain during venipuncture; the pain that a child suffers from illness; such as severe pain; fracture or tumor pain; the child is not feverish; no history of surgery; no history of intravenous and intramuscular injection; Unwilling to continue participating in the study, Touch sensitivity, failure to venipuncture the first time

Intervention groups

In the intervention group, a simple foot massage is applied immediately before venipuncture for 5 minutes.

In Control group: no intervention

Main outcome variables

Pain; pulse rate; oxygen saturation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190130042555N1**

Registration date: **2019-09-30, 1398/07/08**

Registration timing: **registered_while_recruiting**

Last update: **2019-09-30, 1398/07/08**

Update count: **0**

Registration date

2019-09-30, 1398/07/08

Registrant information

Name

Tayebeh Hasantehrani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 0150

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2019-11-22, 1398/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of foot massage on pain severity due to intravenous catheter insertion in hospitalized preschool children at pediatric ward of Hamadan Besat Hospital 2019

Public title

The effect of foot massage on pain severity due to intravenous catheter insertion in hospitalized preschool children

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Child hospitalized 3 to 6 years Organ and skin health in the legs No analgesic medication for 3 hours before venipuncture A child's consciousness of place and time and person Lack of mental retardation No respiratory problems No congenital heart disease First time hospitalized child The second time Venipuncture No acute pain during Venipuncture The pain that a child suffers from illness Such as severe pain Fracture or tumor pain The child is not feverish No history of surgery No history of intravenous and intramuscular injection

Exclusion criteria:

Unwilling to continue participating in the study Touch sensitivity Failure to Venipuncture the first time

AgeFrom **3 years** old to **6 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **60****Randomization (investigator's opinion)**

Not randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

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

Ethics committee of Hamadan University of Medical Sciences

Street address

Hamadan University of Medical Sciences, Research Square, Shahid Fahmideh Ave

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Province

Hamadan

Postal code

6517838698

Approval date

2019-05-18, 1398/02/28

Ethics committee reference number

IR.UMSHA.REC.1398.147

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

Pain

ICD-10 code

G89.1

ICD-10 code description

Acute pain, not elsewhere classified

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

The effect of foot massage on pain Severity due to Intravenous catheter insertion

Timepoint

During venipuncture, two minutes after venipuncture

Method of measurement

Pain Assessment Scale (FLACC) (Face, Leg, Activity Cry, Consolability)

2**Description**

Pulse rate

Timepoint

Before venipuncture, during venipuncture, two minutes after venipuncture

Method of measurement

Device of pulse oximeter

3**Description**

Arterial Oxygen Saturation Percentage

Timepoint

Before venipuncture, during venipuncture, two minutes after venipuncture

Method of measurement

Device of pulse oximeter

Secondary outcomes

1

Description

Pain

Timepoint

During venipuncture, two minutes after venipuncture

Method of measurement

Pain Assessment Scale (FLACC) (Face, Leg, Activity, Cry, Consolability)

Intervention groups

1

Description

Intervention group: Intervention includes simple foot massage. It is performed on children aged 3 to 6 years in the pediatric ward and before venipuncture. In the experimental group, if they meet the inclusion and exclusion criteria, the child will go to the examination room with the mother. First, the child's physiological parameters, including heart rate and blood oxygen saturation, will be recorded using a calibrated pulse oximeter. Then the simple foot massage for 5 minutes is given. The method is to massage the child lying on the bed, and researcher at the bottom of your feet and hands with baby oil fatty child is the first all parts of the foot; the foot; heel and toes gently massage. Take the Foot with one hand and press the foots slowly with the other. With one thumb is make rotational movements of the heel. It performs movements in both legs. Immediately after the massage Venipuncture performed. And at the beginning of venipuncture, IV arrival time to the skin, pain assessment scale FLACC will be completed by the researcher and physiological parameters will be recorded. Physiological indices are recorded again two minutes after venipuncture and pain assessment scale FLACC will be completed by the researcher.

Category

Prevention

2

Description

Control group: In the Control group if you have to study inclusion and exclusion criteria. Child with his mother will go in the examination room. The control group did not Intervention, and children receive routine care, then the child's physiological indicators including heart rate and blood oxygen saturation using a calibrated pulse oximetry will be recorded. And at the beginning of venipuncture, IV arrival time to the skin, pain assessment scale FLACC will be completed by the researcher and physiological parameters will be recorded. Two minutes after venipuncture, physiological parameters will be recorded again and the FLACC pain scale will be completed by the researcher.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hamadan besat hospital

Full name of responsible person

Tayebeh Hasan Tehrani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr saeid bashirian

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Hamedan, In front of Mardom Park, Hamedan University of Medical Sciences, Research and Technology Vice-Chancellor

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bashirian@umsha.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Hamedan 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

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

Hamedan University of Medical Sciences

Full name of responsible person

Tayebeh Hasan Tehrani

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Position

student

Latest degree

Bachelor

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Full name of responsible person

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Latest degree

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Other areas of specialty/work

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Phone**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