Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of two methods of warm wet compresses and Epsom salt spray on reducing infiltration, phlebitis and peripheral venous pain in children

Protocol summary

Study aim
Comparison of the effect of Epsom salt spray and wet hot compress on the rate of infiltration, phlebitis and peripheral venous pain in children

Design
This study is a clinical trial with a control group, with parallel, double-blind, randomized phase 3 groups that will be performed on 114 children with phlebitis, infiltration and pain caused by peripheral venous catheter. Participants will be assigned in three groups (two internal groups and one control group) randomly with triple blocks.

Settings and conduct
This study will be performed on children admitted to the pediatric, surgical and emergency department of Allameh Bohlool Gonabadi Hospital. The children with venous complication, after obtaining the consent to participate in the study, are randomly divided into three groups: Epsom Salt spray, hot compress and control. The intervention will be performed as mentioned and then the data will be compared in three groups.The present study is a two-way blind study and the data collector, analyst and individuals under study will not be aware of the allocation of groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Children older than 6 months. Having peripheral venous complications based on relevant scales. Consent of one of the parents to participate in the project. Exclusion criteria: Having a history of skin allergies. Having open wounds in the study area. Having kidney failure.

Intervention groups
In intervention groups, wet hot compress or Epsom salt solution is placed in the involved position for 20 minutes. This intervention will be performed every 6 hours, and each time after the intervention at the end of 24 hours after the complication the pain, infiltration and phlebitis of the child will be measured.

Main outcome variables
Reduction of phlebitis, infiltration and pain caused by peripheral venous catheter

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201107049290N1**
Registration date: **2021-01-16, 1399/10/27**
Registration timing: **registered_while_recruiting**

Last update: **2021-01-16, 1399/10/27**
Update count: **0**

Registration date
2021-01-16, 1399/10/27

Registrant information

Name
Fatemeh HosseiniMoghaddam

Name of organization / entity

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Iran (Islamic Republic of)

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+98 51 5722 3028

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-11-21, 1399/09/01

Expected recruitment end date
2021-05-21, 1400/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of two methods of warm wet compresses and Epsom salt spray on reducing infiltration, phlebitis and peripheral venous pain in children

Public title

The effect of Epsom spray on infiltration, phlebitis and peripheral venous pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children older than 6 months, Having peripheral venous complications based on relevant scales. Consent of one of the parents to participate in the project,

Exclusion criteria:

Having a history of skin allergies Having open wounds in the study area Having kidney failure

Age

From **6 months** old to **14 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **114**

Randomization (investigator's opinion)

Randomized

Randomization description

Children with peripheral venous complication will be selected based on inclusion criteria. Participants will be assigned to three groups using the permutation block method. In this study, the letter A is considered as intervention group 1 (Epsom salt spray), the letter B as intervention group 2 (hot compress) and the letter C as the control group. The size of each block is 3 people, the total number of blocks is 30 and the possible permutations are 6 modes. A code will be assigned to each of the triple blocks; Thus ABC is given code 1, ACB code 2, BAC code 3, BCA code 4, CAB code 5 and CBA code 6. Then, using "random number table" the order of assigning people in groups ,by selecting a random number and then scrolling down, will be obtained. If the number was between 1 and 6, the state related to that code is recorded, and if it was from zero and 7 to 9, the next number is selected. This will continue until the required sample size is completed.

Blinding (investigator's opinion)

Double blinded

Blinding description

For data blinding, the data collector, the analyst, and the subjects will not be aware of the allocation of groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Gonabad University of Medical Sciences

Street address

Saadi Town, 14 Golhaei St., No. 14

City

Gonabad

Province

Razavi Khorasan

Postal code

9691938775

Approval date

2020-10-11, 1399/07/20

Ethics committee reference number

IR.GMU.REC.1399.080

Health conditions studied

1

Description of health condition studied

Infiltration and phlebitis caused by peripheral venous catheter

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Degree of infiltration

Timepoint

Determination of infiltration degree before intervention, 6, 12 and 24 hours after intervention

Method of measurement

Pediatric peripheral intravenous infiltration assessment tool

2

Description

Phlebit degree

Timepoint

Determination of Phlebit degree before intervention, 6,

12 and 24 hours after intervention

Method of measurement

Phlebit Visual Scale

3

Description

Pain score

Timepoint

Determination of Pain score before intervention, 6, 12 and 24 hours after intervention

Method of measurement

Face, Legs, Activity, Cry, Consolability scale (FLACC scale)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: In this group, gas impregnated with Epsom salt solution is placed in the involved position for 20 minutes. Epsom salt solution will be prepared by the researcher by combining 20 grams of magnesium sulfate salt with 100 cc of distilled water and stored at room temperature.This intervention will be performed for the child two more times, every 6 hours, and each time after the intervention, the pain, infiltration and phlebitis of the child will be measured.

Category

Treatment - Other

2

Description

Intervention group2: In this group, hot compresses are placed in the involved position for 20 minutes. This intervention will be performed for the child two more times, every 6 hours, and each time after the intervention, the pain, infiltration and phlebitis of the child will be measured.

Category

Treatment - Other

3

Description

Control group: No special intervention has been performed for this group and they will be examined only for pain, infiltration and phlebitis.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Allameh Bohlool Gonabadi Hospital

Full name of responsible person

Fatemeh HosseiniMoghddam

Street address

Parstar Blvd. Allameh Bohlool Gonabadi Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Shahla Khosravan

Street address

Asian roadside. Gonabad University of Medical Sciences. Deputy of research and technology

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Grant name

Grant code / Reference number

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

No

Title of funding source

Allameh Bohlool Gonabadi Hospital

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

Gonabad University of Medical Sciences

Full name of responsible person
Fatemeh HosseiniMoghaddam
Position
Faculty instructor
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Master
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Person responsible for scientific inquiries

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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