Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 2026

Comparison of two methods of Aloe Vera compress and hot compress on pain and degree of intravenous catheter phlebitis in children hospitalized in pediatric wards

Protocol summary

Study aim
Comparison of two methods of aloe vera compress and hot compress on pain and degree of phlebitis caused by venous catheter in children.

Design
This clinical trial consists of three parallel groups of 90 patients. The law of random allocation was used for randomization. The trial phase is not applicable in this study due to the lack of drug use.

Settings and conduct
This study will be performed on children admitted to the pediatric wards of Ali Ibn Abitaleb Hospital in Zahedan. The intervention will be performed as mentioned above and then the mean data before and after the intervention will be compared in three groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: No underlying diseases such as diabetes, asthma and skin diseases, Has an antibiotic regimen other than vancomycin, No reaction or allergy to aloe vera gel or hot compresses, 3-8 years old, Has the necessary consciousness and ability to participate in research, Have Phlebitis due to venous catheter from grade 1 to 5, Written parental consent, Not too much pain and unbearable due to phlebitis. Exclusion criteria: Discharge from hospital three days before the start of the study, Reluctance to continue cooperation in the study, Illness of the patient for any reason, Exacerbation of phlebitis symptoms and pain.

Intervention groups
The intervention groups in this study consist of three groups. The first group that uses aloe vera compress. The second group that uses hot compresses. The third group is the control group that does not receive any intervention.

Main outcome variables
The degree of change in the degree of phlebitis compared to before the study

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220427054677N1**
Registration date: **2022-06-05, 1401/03/15**
Registration timing: **prospective**

Last update: **2022-06-05, 1401/03/15**
Update count: **0**

Registration date
2022-06-05, 1401/03/15

Registrant information

Name
Foruzan Hajiabadi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 5372 1077

Email address
rezvanhajiabadi16@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-07-11, 1401/04/20

Expected recruitment end date
2022-10-12, 1401/07/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of two methods of Aloe Vera compress and hot compress on pain and degree of intravenous catheter phlebitis in children hospitalized in pediatric wards

Public title
Comparison of the effect of Aloe Vera compress and warm compress on pain and phlebitis

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Lack of underlying diseases such as diabetes, asthma and skin diseases Having an antibiotic regimen other than vancomycin No allergic reaction to aloe vera compress and hot compress Age 3-8 years Has the necessary awareness and ability to participate in research Having phlebitis due to venous catheter from grade 1-5 Parental written consent Not too much pain and unbearable due to phlebitis

Exclusion criteria:
Discharge from hospital three days before the start of the study Reluctance to continue collaborating in the study Lack of proper and timely use of aloe vera compress or hot compress during the study Illness for any reason Exacerbation of phlebitis symptoms and pain in the patient

Age
From **3 years** old to **8 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
The sampling method is that first the control group is taken (30 pieces) and then for the group of interventions we act according to the method of random allocation law in such a way that 60 color cards (30 pieces of blue color card for the intervention group and 30 pieces) Put the red color card for the intervention group (warm compress) in a box and based on the exit of the color cards by the mother of the eligible sick child, it will be placed in the intervention groups.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Sistan and Baluchestan University of Medical Sciences and Health Services

Street address
Medical Sciences Campus, Dr. Hesabi Square, zahedan

City
zahedan

Province
Sistan-va-Balouchestan

Postal code
9816743463

Approval date
2021-05-09, 1400/02/19

Ethics committee reference number
IR.ZAUMS.REC.1401.059

Health conditions studied

1

Description of health condition studied
Children with phlebitis and pain from a venous catheter

ICD-10 code
180

ICD-10 code description
Phlebitis and thrombophlebitis

Primary outcomes

1

Description
The degree of change in the degree of phlebitis compared to before the study

Timepoint
24 hours and 48 hours and 72 hours after the start of the intervention

Method of measurement
Iranian Nursing Association Phlebitis Degree Observation Checklist

2

Description
The degree of change in pain score compared to before the study

Timepoint
24 hours and 48 hours and 72 hours after the start of the intervention

Method of measurement
"Wong Baker" Pain Image Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: In this group, the researcher first wears disposable gloves and impregnates a sterile gauze with 5 cc of aloe vera gel (brand Kaman of Ceylan Sabz Company) which has been drawn with a syringe, and then on the place of the child's phlebitis. And then cover the area with a bandage for 20 minutes. This intervention will be repeated every 12 hours to 3 days (at 0,12, 24, 36, 48, 60, 72 hours after the intervention).

Category
N/A

2

Description
Intervention group 2: In this group, first the heat jelly pack (model 810 or Sina Hakim, size 8 * 10) will be placed in the microwave for 20-60 seconds, and then the pack will be gently pushed out by a gas. The temperature will be checked with a digital thermometer, the temperature of which is 37-38 degrees Celsius, then the pack will be covered with sterile gas and placed on the phlebite for 20 minutes. This intervention will be repeated every 12 hours to 3 days (at 0,12, 24, 36, 48, 60, 72 hours after the intervention).

Category
N/A

3

Description
Control group: no intervention will be performed and like the other two groups (in the time of 0, 24, 48, 72 hours) the degree of phlebitis and pain score will be recorded in them.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Ali Ibn Abitaleb Hospital, Zahedan

Full name of responsible person
Foruzan Hajiabadi

Street address
Medical Sciences Campus, Dr. Hesabi Square, zahedan

City
Zahedan

Province
Sistan-va-Balouchestan

Postal code
9816743463

Phone
+98 54 3337 2151

Fax
+98 54 3337 2151

Email
rezvanhajiabadi16@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Zahedan University of Medical Sciences

Full name of responsible person
Mahin Naderifar

Street address
Medical Sciences Campus، Dr. Hesabi Square, zahedan

City
Zahedan

Province
Sistan-va-Balouchestan

Postal code
9816743463

Phone
+98 54 3337 2151

Email
mahin.naderifar@gmail.com

Grant name

Grant code / Reference number

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

Title of funding source
Zahedan University of Medical Sciences

Proportion provided by this source
40

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
Zahedan University of Medical Sciences

Full name of responsible person
Foruzan Hajiabadi

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
Medical Sciences Campus, Dr. Hesabi Square, zahedan

City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Phone
+98 54 3337 2151
Email
rezvanhajiabadi16@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Foruzan Hajiabadi
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Medical Sciences Campus, Dr. Hesabi Square, zahedan
City
zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Phone
+98 54 3337 2151
Email
rezvanhajiabadi16@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Foruzan Hajiabadi
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Medical Sciences Campus, Dr. Hesabi Square, zahedan
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Phone
+98 54 3337 2151
Email
rezvanhajiabadi16@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Informed consent obtained from patients is only for the use of their information in this study, so they may not be satisfied for other people to access their information even if not identified.
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
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
In this study, the results of patient data analysis will be published briefly.
When the data will become available and for how long
Start access after publishing results.
To whom data/document is available
Because patients' personal data is not published, all researchers and interested parties can access the results of data analysis.
Under which criteria data/document could be used
Only plan managers, consultants and analysts are allowed access to patient data.
From where data/document is obtainable
To receive the documents, refer to Zahedan University of Medical Sciences and Health Services at the address of Zahedan, Dr. Hesabi Square, campus of the University of Medical Sciences, to Dr. Mahin Naderifar.
What processes are involved for a request to access data/document
To access the data, if necessary to use the new study plan, first a proposal for a new plan must be prepared and approved by the relevant research ethics committee, and after obtaining the code of ethics to Zahedan University of Medical Sciences and Health Services at Zahedan, Dr. Hesabi Square, campus of the University of Medical Sciences, refer to Dr. Mahin Naderifar.
Comments
None