Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of Intravenous House Ultra Dressing in Reducing Pediatric Phlebitis In pediatric Wards :A randomized controlled trial (RCT)

Protocol summary

Study aim
1. To determine the affect of intravenous house Ultra Dressing in reducing pediatric phlebitis in pediatric wards. 2. To find out the relationship between the affect of I.V. House Ultra Dressing and sociodemographic characteristics of children such as age, sex, weight, and others.

Design
A RCT (randomized controlled trial)

Settings and conduct
The study will take place in the pediatric wards of Balad General Hospital and Tikrit Teaching Hospital. These settings are chosen due to their high patient volume and prevalence of peripheral intravenous catheter (PIVC) use, including 60 patients the divided two groups

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. Pediatric patient aged 0-3years. 2. Patient with IV catheter dwell time exceeding 48 hours. 3. Intravenous therapy. Exclusion criteria 1. Patients with existing phlebitis or skin infections. 2. Patient with known allergies or reaction to the material used in the ultra-dressing. 3. Pediatric patients older than 3 years. 4. Patients with chronic vascular or immune system conditions that could influence the development of phlebitis. 5. Patients with IV catheters for less than 48 hours.

Intervention groups
This stage begins with application of the I.V. House Ultra Dressing on peripheral intravenous catheters (PIVCs) in reducing pediatric phlebitis using the Visual Infusion Phlebitis Scale (VIPS) to assess phlebitis severity.

Main outcome variables
pediatric phlebitis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241123063810N1**
Registration date: **2024-12-15, 1403/09/25**
Registration timing: **registered_while_recruiting**

Last update: **2024-12-15, 1403/09/25**
Update count: **0**

Registration date
2024-12-15, 1403/09/25

Registrant information

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-12-01, 1403/09/11

Expected recruitment end date
2025-02-01, 1403/11/13

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of Intravenous House Ultra Dressing in Reducing Pediatric Phlebitis In pediatric Wards :A randomized controlled trial (RCT)

Public title
Pediatric Phlebitis In pediatric Wards
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
1. Pediatric patient aged 2 months to 3 years. 2. Patient with IV catheter dwell time exceeding 48 hours. 3. Intravenous therapy.
Exclusion criteria:
1. Patients with existing phlebitis or skin infections. 2. Patient with known allergies or reaction to the material used in the ultra-dressing. 3. Pediatric patients older than 3 years. 4. Patients with chronic vascular or immune system conditions that could influence the development of phlebitis. ents with IV catheters for less than 48 hours.
Age
From **2 months** old to **3 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Tools used in randomization such as table of random numbers, computer softwares, etc
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
Research Ethical Approval Committee, at the College of Nursing
Street address
Celebration Strees
City
Tikrit
Postal code
34011
Approval date
2024-11-06, 1403/08/16
Ethics committee reference number
30

Health conditions studied

1

Description of health condition studied
Phlebitis management-related intravenous cannulation
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Reducing phlebitis in pediatrics
Timepoint
The patient's response is assessed for phlebitis within three days of applying the intravenous cannula dressing.
Method of measurement
Phlebitis is assessed in pediatrics using the Visual Infusion Phlebitis Scale (VIPS) to assess phlebitis severity. within three days of applying the intervenous cannula dressing.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: After obtaining the patient's consent and explaining the use of the IV House UltraDressing, the dressing is applied over the IV cannula site immediately after cannulation. The dressing is secured according to the manufacturer's instructions. The researcher assesses the cannula site for signs of phlebitis daily for three days using the Visual Infusion Phlebitis (VIP) scale.
Category
Treatment - Devices

2

Description
Control group: The intravenous catheter was inserted using the hospital's standard dressing without any intervention or application by the researcher. The nurse assisting the researcher in the pediatric ward performed the standard procedure, and the researcher assessed phlebitis daily for three days using the Visual Infusion Phlebitis (VIP) scale.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Balad General Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Web page address
https://conursing.uobaghdad.edu.iq/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
The author of the trial is the funding source
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
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
College of Nursing, University of Baghdad
Full name of responsible person
Roaa Qaseem Mohammed
Position
student
Latest degree
Master
Other areas of specialty/work
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Person responsible for updating data

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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
Undecided - It is not yet known if there will be 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 researcher is acknowledging the scientific community to have verifiable findings of the study. sharing plan includes making all the related data available through publishing the study report in peer-reviewed reputable journals
When the data will become available and for how long
God willing, once finishing the process of data collection, analysis and successfully publishing the manuscript, all the related files will become available for 6 months after publications
To whom data/document is available
All the related files will be shared with any scientific interested parties.
Under which criteria data/document could be used
It may be used after seeking the author's permission and acknowledging his contribution.
From where data/document is obtainable
The author's professional email, which will be available with the published manuscript, can be used to contact the author. e-Mail:ruaa.abd2304m@conursing.uobaghdad.edu.iq
What processes are involved for a request to access data/document
N/A
Comments
The IRCT members deserve sincere gratitude for their sincere efforts to support researchers in achieving their academic goals.