

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Name

Roaa Qaseem

Name of organization / entity

University of baghdad

Country

Iraq

Phone

+964 781 862 5817

Email address

ruaa.abd2304m@conursing.uobaghdad.edu.iq

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. Patients 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 Streets

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 intravenous 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

Roaa Qaseem Mohammed

Street address

Celebration Streets

City

Tikrit

Postal code

34011

Phone

+964 781 862 5817

Email

ruaa.abd2304m@conursing.uobaghdad.edu.iq

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

College of Nursing, University of Baghdad

Full name of responsible person

Asmahan Qasim Mohammed

Street address

Bab Al-Muadham Street

City

Bab Al- Muadham

Postal code

10047

Phone

+964 751 326 1022

Email

asmahankasim@conursing.uobaghdad.edu.iq

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

Nursing

Street address

Celebration Streets

City

Tikrit

Province

Salah din

Postal code

34011

Phone

+964 781 862 5817

Fax**Email**

ruaa.abd2304m@conursing.uobaghdad.edu.iq

Web page address

Person responsible for scientific 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

Nursing

Street address

Celebration Streets

City

Tikrit

Province

Salah din

Postal code

34011

Phone

+964 781 862 5817

Fax**Email**

ruaa.abd2304m@conursing.uobaghdad.edu.iq

Web page address

Person responsible for updating data

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

Nursing

Street address

Celebration Streets

City

Tikrit

Province

Salah din

Postal code

34011

Phone

+964 781 862 5817

Fax**Email**

ruaa.abd2304m@conursing.uobaghdad.edu.iq

Web page address**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.