

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Comparison the effectiveness of Cryotherapy, EMLA Cream, and Lidocaine Spray to Reduce Pain during Arteriovenous Fistula Puncture among clients undergoing hemodialysis

Protocol summary

Study aim

To compare the effectiveness of three pain reliving techniques (cryotherapy, EMLA cream, or lidocaine spray) to reduce pain during arteriovenous fistula puncture in clients undergoing hemodialysis

Design

An experimental multi-center study design with three parallel groups, randomized trial, open-label (unblinded). The minimum sample size for each group will be 28 with a total of 112 subjects

Settings and conduct

Seven hemodialysis centers in seven hospitals (Al-Hussein Medical City, Imam Al-Hassan Al-Mujtaba Hospital, Hussein Teaching Hospital, Al-Karama, Al-Kadhumain Teaching, Al-Kindy Teaching Hospital, Baghdad Teaching Hospital) in four different cities across Iraq

Participants/Inclusion and exclusion criteria

The inclusion criteria for this study were; clients with more than 18 years old, being under hemodialysis at least for three months, conscious and alert, and be able to sign the written informed consent. Clients were excluded under the following criteria; cold intolerance, allergy from local anesthetics or topical medications, upper extremities paralysis, and pregnant or lactating females.

Intervention groups

There will be three intervention groups; Ice pack, EMLA cream, and lidocaine. For ice pack group, 5 cubs of ice (4 × 2 × 2 cm) will placed in a plastic bag and covered with a layer of cotton cloth for five minutes on the site of arteriovenous fistula (AVF). For EMLA group, 1.5 g of EMLA cream will be applied to six cm² on the area of AVF for 20 minutes before the AVF puncture. For lidocaine group, three sprinklings of lidocaine spray will be sprayed before the AVF puncture for five minutes. After the intervention for each group, the needle will be

inserted by the ward nurse, and the pain will be assessed immediately after the needle insertion by using Visual Analogue Scale.

Main outcome variables

Reduce pain during arteriovenous fistula puncture

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200429047244N2**

Registration date: **2022-02-02, 1400/11/13**

Registration timing: **registered_while_recruiting**

Last update: **2022-02-02, 1400/11/13**

Update count: **0**

Registration date

2022-02-02, 1400/11/13

Registrant information

Name

Mohammed Baqer Al-Jubouri

Name of organization / entity

University of Baghdad

Country

Iraq

Phone

+964 1 457 6876

Email address

maaljubouri@conursing.uobaghdad.edu.iq

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-01, 1400/11/12

Expected recruitment end date

2022-06-30, 1401/04/09
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison the effectiveness of Cryotherapy, EMLA Cream, and Lidocaine Spray to Reduce Pain during Arteriovenous Fistula Puncture among clients undergoing hemodialysis

Public title
Using Cryotherapy, EMLA Cream, and Lidocaine Spray to Reduce Pain during Arteriovenous Fistula Puncture: A Randomized Clinical Trial

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
clients with more than 18 years old being under hemodialysis at least for three months being conscious and alert be able to sign the written informed consent
Exclusion criteria:
clients who are cold intolerance clients who have allergy from local anesthetics or topical medications Clients who have upper extremities paralysis pregnant or lactating females

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **86**

Randomization (investigator's opinion)
Randomized

Randomization description
A simple randomization sampling method will be used to assign the study sample in four groups: ice pack, EMLA cream, lidocaine spray, and a control group. Simple randomization is an appropriate method to be used in this clinical trial to increase the probability and reduce and bias. A sealed envelope contained four colors (red, blue, green, and yellow) will be given to each client to choose one color. The clients were allocated to groups based on their colors; red= control, blue= ice pack, green= EMLA cream, and yellow= lidocaine spray. Indeed, four groups will be allocated randomly.

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

Ethics committee in College of Nursing at University of Baghdad

Street address

Bab-AlMuadham

City

Baghdad

Postal code

10053

Approval date

2022-01-23, 1400/11/03

Ethics committee reference number

264

Health conditions studied

1

Description of health condition studied

Arteriovenous Fistula in End-stage Renal Failure

ICD-10 code

I28.0

ICD-10 code description

Arteriovenous fistula of pulmonary vessels

Primary outcomes

1

Description

Pain during arteriovenous fistula puncture in clients undergoing hemodialysis

Timepoint

Immediately after the arteriovenous fistula puncture

Method of measurement

Visual Analogue Scale is a measurement tool that will be used to assess clients' pain.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: 5 cubs of ice (4 × 2 × 2 cm) will be placed in a plastic bag and covered with a layer of cotton cloth for five minutes on the site of AVF. Then, the area will be disinfected by 70% alcohol pads before the AVF puncture. After that, the needle will be inserted by the ward nurse, and the pain will be assessed immediately

after the needle insertion.

Category

Treatment - Other

2

Description

Intervention group2: 1.5 g of EMLA cream (Lidocaine 25 mg and Prilocaine 25 mg, Recipharm Karlskoga) will be applied to six cm2 on the area of AVF for 20 minutes before the AVF puncture. After that, the EMLA cream will be removed, and the area will be disinfected by 70% alcohol pads. Then, the needle will be inserted by the ward nurse, and the pain will be assessed immediately after the needle insertion.

Category

Treatment - Drugs

3

Description

Intervention group3: three sprinklings of lidocaine spray (ElQady, Ankara, Turkey) will be sprayed on the AVF. After five minutes (Bhalla et al., 2009), the area will be disinfected by 70% alcohol pads. Then, the needle will be inserted by the ward nurse, and the pain will be assessed immediately after the needle insertion.

Category

Treatment - Drugs

4

Description

Control group: no procedures will be done before AVF puncture, and the pain will be assessed immediately after the needle insertion.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Hussein Medical City

Full name of responsible person

Karbala Health Directorate

Street address

Maytham Al-Tammar Street

City

Karbala

Postal code

56001

Phone

+964 773 458 0932

Email

Hussein@imam.hussein.1238

Web page address

2

Recruitment center

Name of recruitment center

Imam Al-Hassan Al-Mujtaba Hospital

Full name of responsible person

Karbala Health Directorate

Street address

Bab Al-Murad

City

Karbala

Postal code

56001

Phone

+964 773 765 7648

Email

Hassan-Almujtaba@gmail.com

Web page address

<https://www.facebook.com/%D9%85%D8%B3%D8%A%D8%B4%D9%81%D9%89-%D8%A7%D9%84%D8%A5%D9%85%D8%A7%D9%85-%D8%A7%D9%84%D8%AD%D8%B3%D9%86-%D8%A7%D9%84%D9%85%D8%AC%D8%AA%D8%A8%D9%89-%D8%B9%D9%84%D9%8A%D9%87-%D8%A7%D9%84%D8%B3%D9%84%D8%A7%D9%85-%D8%A7%D9%84%D8%AA%D8%B9%D9%84%D9%8A%D9%85%D9%8A-706446153139402/>

3

Recruitment center

Name of recruitment center

Hussein Teaching Hospital

Full name of responsible person

Al-Muthanna Health Directorate

Street address

Al-Samawa

City

Al-Samawa

Postal code

66001

Phone

+964 790 147 4470

Email

sabah.abd@mu.edu.iq

4

Recruitment center

Name of recruitment center

Al-Karama

Full name of responsible person

Al-Karkh Health Directorate

Street address

Alawy street

City

Baghdad

Postal code

10053

Phone

+964 789 365 4787

Email

hawra-karama87@gmail.com

5

Recruitment center

Name of recruitment center

Al-Kadhumain Teaching Hospital

Full name of responsible person

Baghdad Al-Rusafa Health Directorate

Street address

Al-Kadhemia

City

Baghdad

Postal code

10052

Phone

+964 1 415 8408

Email

gen.health@moh.gov.iq

6

Recruitment center

Name of recruitment center

Al-Kindy Teaching Hospital

Full name of responsible person

Baghdad Al-Rusafa Health Directorate

Street address

Al-Kindy

City

Baghdad

Postal code

10052

Phone

+964 1 415 8408

Email

gen.health@moh.gov.iq

7

Recruitment center

Name of recruitment center

Baghdad Teaching Hospital

Full name of responsible person

Medical City

Street address

Bab Al-Muadham

City

Baghdad

Postal code

10053

Phone

+964 789 365 4787

Email

medicalcity@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of Baghdad

Full name of responsible person

Mohammed Baqer Al-Jubouri

Street address

Bab Al-Muadham

City

Baghdad

Postal code

10054

Phone

+964 1 489 6875

Email

nursing.college.uob@gmail.com

Web page address

<http://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 himself is the funding source.

Proportion provided by this source

100

Public or private sector

Private

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**

University of Baghdad

Full name of responsible person

Mohammed Baqer Al-Jubouri

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursing

Street address

Al-Adhamia, Al-Keriaat

City

Baghdad

Province

Baghdad

Postal code

10053

Phone

+964 1 489 6875

Email

maaljubouri@conursing.uobaghdad.edu.iq

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

University of Baghdad

Full name of responsible person

Mohammed Baqer Al-Jubouri

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursing

Street address

Al-Adhamia, Al-Keriaat

City

Baghdad

Province

Baghdad

Postal code

10053

Phone

+964 1 489 6875

Email

maaljubouri@conursing.uobaghdad.edu.iq

Web page address**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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The data will be the results of Visual Analogue Scale that measure clients' pain during AVF puncture in both control and interventions groups.

When the data will become available and for how long

If the article is published in an open access journal, the data will be available after 6 months of publication. If the article is published in a subscribed journal, the data will be available after one year because of the policy of the subscribed journals.

To whom data/document is available

With academic nurses and any researcher who is interested in the data

Under which criteria data/document could be used

The data could be used after getting the authors' permission via email. Also, users need to acknowledge the owner.

From where data/document is obtainable

Users can ask for the data and the permission via email. Dr. Al-Jubouri is the corresponding author. He will be in contact with whom ask for the data. His email is maaljubouri@conursing.uobaghdad.edu.iq Also, Dr. Al-Jubouri works at University of Baghdad/ College of Nursing. The address is Bab Al-Muadham, Baghdad, Iraq.

What processes are involved for a request to access data/document

Users can ask for the data and the permission via email. Dr. Al-Jubouri is the corresponding author. He will be in contact with whom ask for the data. His email is maaljubouri@conursing.uobaghdad.edu.iq

Comments**Person responsible for updating data****Contact****Name of organization / entity**

University of Baghdad

Full name of responsible person

Mohammed Baqer Al-Jubouri

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursing

Street address

Al-Adhamia, Al-Keriaat

City

Baghdad

Province

Baghdad

Postal code

10053

Phone

+964 1 489 6875

Email

maaljubouri@conursing.uobaghdad.edu.iq