Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

A Comparative Study of Virtual Reality and Shot Blocker Maneuver for Managing Pain, Anxiety, and Vital Signs in Patients During Bone Marrow Aspiration and Biopsy: Randomized Controlled Trail

Protocol summary

Study aim
To compere effects of three maneuver (virtual reality, shot blocker and mixed maneuver).
Design
A factorial group, not blinding, A Randomized control Clinical trial
Settings and conduct
Medical City / Hematology Center / department of bone marrow aspiration in Iraq Single blind in this trial, the participant is kept blinded to their group assignment (interventions and control groups) throughout the study.
Participants/Inclusion and exclusion criteria
Inclusion criteria: adult patient with undergoing bone marrow aspiration and biopsy local anesthetic. Exclusion criteria: the patient’s withdrawal at any stage of the study, not using a virtual reality headset during bone marrow aspiration and biopsy.
Intervention groups
The samples will divide into four groups, first group will use virtual reality with natural video before 5-minute form start procedure, second group will apply shot blocker maneuver on site of insertion bone marrow aspiration device, third group will use two methods (virtual reality and shot blocker maneuver). The fourth group (control group) does not give any intervention.
Main outcome variables
Pain and anxiety and vital signs

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20230310057672N6**
Registration date: **2025-01-29, 1403/11/10**
Registration timing: **prospective**
Last update: **2025-01-29, 1403/11/10**
Update count: **0**
Registration date
2025-01-29, 1403/11/10

Registrant information
Name
Alaa Jawad
Name of organization / entity
University of Baghdad/College of Nursing
Country
Iraq
Phone
+964 1 521 1494
Email address
alaaj@conursing.uobaghdad.edu.iq

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-02-06, 1403/11/18
Expected recruitment end date
2025-03-20, 1403/12/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A Comparative Study of Virtual Reality and Shot Blocker Maneuver for Managing Pain, Anxiety, and Vital Signs in Patients During Bone Marrow Aspiration and Biopsy: Randomized Controlled Trail

Public title
Effect of Virtual Reality and Shot Blocker for Managing

Pain, Anxiety, and Vital Signs

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Adult patient with undergoing bone marrow aspiration and biopsy local anesthetic, having no experience of bone marrow aspiration and biopsy Full consciousness No hearing and vision impairments based on the patient's report.

Exclusion criteria:

The patient's withdrawal at any stage of the study Not using a VR headset during bone marrow aspiration and biopsy Developing clinical instability during the procedure (such as loss of conscious- ness, cardiac and respiratory disorders, nausea, oculomotor issues).

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **223**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization by using four cards blue, red, green, yellow put in the box the blue card represented virtual reality (A group), red card for shot blocker (B group), green card for virtual reality and shot blocker together (AB group), and yellow card for control (C group). Then all participant was allowed to choose one of these cards. No allocation concealment will be carried out.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Factorial

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

Bab AL-Muadum

City

Baghdad

Postal code

10045

Approval date

2024-11-06, 1403/08/16

Ethics committee reference number

34

Health conditions studied

1

Description of health condition studied

Pain

ICD-10 code

G89

ICD-10 code description

Pain, not elsewhere classified

2

Description of health condition studied

Anxiety

ICD-10 code

F06.4

ICD-10 code description

Anxiety disorder due to known physiological condition

3

Description of health condition studied

Changes in vital signs

ICD-10 code

Z01.3

ICD-10 code description

Encounter for examination of blood pressure

4

Description of health condition studied

Vital signs: heart rate

ICD-10 code

R00.0

ICD-10 code description

Tachycardia, unspecified

5

Description of health condition studied

Vital signs: Heart rate

ICD-10 code

R00.1

ICD-10 code description

Bradycardia, unspecified

6

Description of health condition studied

Vital signs: Breathing rate

ICD-10 code

R06

ICD-10 code description

Abnormalities of breathing

Primary outcomes

1

Description
anxiety
Timepoint
Five minutes before bone marrow aspiration - immediately after bone marrow aspiration
Method of measurement
stat-trait anxiety scale (STAS)

2

Description
Changes in vital signs
Timepoint
Five minutes before bone marrow aspiration - during bone marrow aspiration - 5 minutes after bone marrow aspiration
Method of measurement
Portable monitor device.

Secondary outcomes

1

Description
Pain
Timepoint
Immediately after bone marrow aspiration and biopsy.
Method of measurement
Visual analog scale (VAS) The VAS is a reliable, valid, responsive, and frequently used pain outcome measure. It consists of a bidirectional 10 cm straight line with two labels, that is, “no pain” and “worst possible pain”, located at either end of the line. Patients are instructed to draw a vertical mark on the line indicating their pain level The reliability data are VAS, (0.97). whereas (0) means no pain, the closer you are to number (10) means sever pain.

2

Description
Anxiety.
Timepoint
Immediately after bone marrow aspiration and biopsy
Method of measurement
Stat-trait anxiety scale (STAS) The 20-item SAI and the 20-item Trait Anxiety Inventory are independent of each other. In SAI, each item is scored in four-point Likert-type responses as follows: none: 1, a little: 2, a lot: 3, and completely: 4. In the Trait Anxiety Inventory, each item is scored in four-point Likert-type responses: rarely: 1, sometimes: 2, most of the time: 3, and almost always: 4. Higher scores indicate a higher level of anxiety, whereas low scores indicate that the anxiety level is low. In this study, Cronbach’s alpha value of the state anxiety inventory was found to be 0.937

3

Description
Vital signs (HR, BP, RR and SPo2) during procedure
Timepoint
Immediately after bone marrow aspiration and biopsy
Method of measurement
Portable monitor device: Vital signs are measured during and immediate after bone marrow aspiration and biopsy (Patient's device manufacturer: Comen Magic Country: India Model: C86 Serial Number Kf200723063f).

Intervention groups

1

Description
Intervention group (A): virtual reality (VR) technology only, this group received virtual reality technology using Samsung gear VR The patient is placed in the prone position and the virtual reality goggles are placed on the patient's head before the bone marrow aspiration and biopsy procedure begins, where a video containing natural scenes is shown through the VR glosses and calm music. After the procedure is completed, the patient's pain are measure by visual analog scale, anxiety are measure by stat-trait anxiety scale (STAS) The 20-item SAI and vital signs are measure by portable monitor device.
Category
Treatment - Other

2

Description
Intervention group (B): The ShotBlocker is a diminutive, flat, U-shaped plastic apparatus adorned with rounded protuberances. It is applied to the skin during the administration of injections and operates by stimulating the nerve endings situated around the injection site. This tactile stimulation is posited to alleviate pain by temporarily obstructing the conveyance of pain signals to the central nervous system. ShotBlocker put on site of needle insertion of bone marrow aspiration device. After the procedure is completed, the patient's pain are measure by visual analog scale, anxiety are measure by stat-trait anxiety scale (STAS) The 20-item SAI and vital signs are measure by portable monitor device.
Category
Treatment - Other

3

Description
Intervention group (AB): virtual reality technology and ShotBlocker maneuver use during procedure and After the procedure is completed, the patient's pain are measure by visual analog scale, anxiety are measure by stat-trait anxiety scale (STAS) The 20-item SAI and vital signs are measure by portable monitor device.
Category
Treatment - Other

4

Description
Control group (C): Subjects in the control group with bone marrow aspiration and biopsy. No intervention was provided during the study. . After the procedure is completed, the patient's pain are measure by visual analog scale, anxiety are measure by stat-trait anxiety scale (STAS) The 20-item SAI and vital signs are measure by portable monitor device

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Department of bone marrow aspiration / Hematology Center / Medical City

Full name of responsible person
Alaa Jawad Kadhim, Tahseen Faleh

Street address
Baghdad, Street 729

City
Baghdad

Postal code
10045

Phone
+964 770 352 0314

Email
alaaj@conursing.uobaghdad.edu.iq

Web page address
https://www.medicalcity.gov.iq/ar/contact-us

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
University of Baghdad/College of Nursing

Full name of responsible person
Professor. Wissam Jabbar Qasim, PhD. Dean

Street address
Bab AL-Muadum campus

City
Baghdad

Postal code
10001

Phone
+964 1 521 1494

Email
alaaj@conursing.uobaghdad.edu.iq

Web page address
https://en.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 authors of the trial are 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
University of Baghdad/college of Nursing

Full name of responsible person
Alaa Jawad Kadhim

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursing

Street address
Baghdad, Street 729

City
Baghdad

Province
Alrusafa

Postal code
10045

Phone
+964 770 352 0314

Email
alaaj@conursing.uobaghdad.edu.iq

Web page address
https://mapcarta.com/30678848

Person responsible for scientific inquiries

Contact

Name of organization / entity
University of Baghdad/college of Nursing

Full name of responsible person
Alaa Jawad Kadhim

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursing

Street address
Baghdad, Street 729

City
Baghdad

Province
Alrusafa

Postal code
10045
Phone
+964 770 352 0314
Email
alaaj@conursing.uobaghdad.edu.iq
Web page address
https://mapcarta.com/30678848

Person responsible for updating data

Contact
Name of organization / entity
University of Baghdad/college of Nursing
Full name of responsible person
Alaa Jawad Kadhim
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursing
Street address
Baghdad, Street 729
City
Baghdad
Province
Alrusafa
Postal code
10045
Phone
+964 770 352 0314
Email
alaaj@conursing.uobaghdad.edu.iq
Web page address
https://en.conursing.uobaghdad.edu.iq/

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
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
The data will be results of comparing the effect between intervention and control groups using reliable measures.
When the data will become available and for how long
God willing, once finishing the process of data collection, analysis, and successful publishing of the manuscript, all the related files will become available for five months after the publications, after you are approved to register on the Iranian clinical trials website
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 e-mail that will be available with the published manuscript can be used to contact the author. e-Mail: alaaj@conursing.uobaghdad.edu.iq
What processes are involved for a request to access data/document
The processes involved in accessing this documentation are possible via email: alaaj@conursing.uobaghdad.edu.iq, the first and last name of authors, trial' title variable and the trial Id.
Comments
Profound appreciations are due to the IRCT members for their genuine efforts in helping researchers fulfilling their academic endeavors. The four groups were added individually in each field. We hope that the modifications will be appropriate to the design of the experiment. With many thanks and appreciation for your patience.