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Using ultrasound to guide placement of a tube in a vein in the arm or leg

Submission date
04/01/2022

Recruitment status
No longer recruiting

Registration date
05/01/2022

Overall study status
Completed

Last Edited
27/01/2025

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Peripheral intravenous access is required to insert a tube into a vein to administer fluids or medication.
Peripheral intravenous access is a common clinical procedure, and difficult peripheral intravenous access is a common problem in caring for emergency and critically ill patients. During difficult intravenous access in clinical practice, the timeliness of immediate treatment is affected, endangering the patient's safety. Repeated injections increase pressure on nursing staff and consume more nursing hours and medical costs. Accordingly, this study aimed to test the effect of ultrasound guidance in difficult peripheral intravenous access.

Who can participate?
Adult volunteers aged 20 years or above, with difficult intravenous access.

What does the study involve?
This study was a randomized crossover study. Each individual underwent ultrasound-guided and traditional blind peripheral intravenous access in alternation. Individuals in Group A underwent ultrasound-guided intravenous cannulation in the right arm and traditional intravenous cannulation in the left arm, while individuals in Group B underwent traditional intravenous cannulation in the right arm and ultrasound-guided intravenous cannulation in the left arm. All participants receive the same outcome measurements, including Overall success rate, First attempt success rate, Number of attempts, Procedure time, Side effect incidence rate.

What are the possible benefits and risks of participating?
The possible benefits are the ultrasound-guided peripheral intravenous access protocol can improve the first attempt success rate, overall success rate and reduce the number of attempts. The possible risks include injection pain and bleeding, which are the same to the control group of traditional blind peripheral intravenous access.

Where is the study run from?
Chi-Mei medical center (Taiwan)

When is the study starting and how long is it expected to run for?
November 2017 to November 2019

Who is funding the study?
Taiwan nurses association

Who is the main contact?
Chia-Chi Kuo, kuochiachi63@gmail.com

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Ultrasound-guided peripheral intravenous access in adults: a randomized crossover controlled trial

Study objectives

Ultrasound guidance could significantly improve the first attempt success rate, overall success rate, and reduce the number of attempts in difficult peripheral intravenous access.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/01/2018, Institutional review board of Chi-Mei medical center (No.901, Zhonghua Rd., Yongkang Dist., Tainan City 710, Taiwan; +886(6)2812811#53720; csr2930@mail.chimei.org.tw), ref: 10612-002.

Study design
Interventional randomized crossover study

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Effects of ultrasound-guided peripheral intravenous access protocol on first attempt success rate, overall success rate, and number of attempts in patients with difficult peripheral intravenous access.

Interventions
This study was a non-blinded, randomized crossover study. Convenient sampling was applied to enroll 36 adult volunteers with the problem of difficult peripheral intravenous access (with a score of 3 or 4 for difficult intravenous access, i.e. with invisible but palpable veins or invisible and impalpable veins) in a medical center in southern Taiwan. The random sequence was generated by block randomization and was concealed in a sealed envelope. Each individual underwent ultrasound-guided and traditional blind peripheral intravenous access in alternation. Ultrasound-guided peripheral intravenous access was performed using a high-frequency 12 MHz ultrasound probe, and a two-person, dynamic, and longitudinal and transversal scanning method was adopted to help locate the position, direction, and depth of the peripheral vein.

Intervention Type
Procedure/Surgery

Primary outcome measure
Data collected during the injection process:
1. First attempt success rate

2. Overall success rate
3. Number of attempts

Secondary outcome measures
Data collected during the injection process:
1. Procedure time
2. Side effect incidence rate

Overall study start date
27/11/2017

Completion date
30/11/2019

Eligibility

Key inclusion criteria
1. Volunteers with difficult intravenous access: This study used the difficult intravenous access score (Benkhadra et al., 2012) to evaluate the degree of difficult intravenous access of the participants, with a score of 1 indicating visible and palpable veins, a score of 2 indicating visible but impalpable veins, a score of 3 indicating invisible but palpable veins, and a score of 4 indicating invisible and impalpable veins. Those with an evaluation score result of 3 or 4 were classified as having difficult intravenous access
2. Adults aged over 20 years, without visual, hearing, or mental disorders
3. Those who were alert and conscious and can communicate in Mandarin or Taiwanese
4. Those who are literate with at least an elementary education

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
36

Total final enrolment
36

Key exclusion criteria
1. Peripheral neurovascular disorders
2. Peripheral local tissue inflammatory diseases
3. Contraindications of peripheral intravenous access

Date of first enrolment
15/12/2018

Date of final enrolment
30/11/2019

Locations

Countries of recruitment
Taiwan

Study participating centre
Chi-Mei medical center
No.901, Zhonghua Rd.
Yongkang Dist.
Tainan City
Taiwan
710

Sponsor information

Organisation
Taiwan Nurses Association

Sponsor details
4F., No. 281, Sec. 4
Xinyi Rd.
Da'an Dist.
Taipei
Taiwan
106439
+886-02-27552291
twna@twna.org.tw

Sponsor type
Other

Website
https://www.twna.org.tw/

ROR
https://ror.org/02px13636

Funder(s)

Funder type

Other

Funder Name
Taiwan Nurses Association

Alternative Name(s)
, TWNA

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
Taiwan

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/02/2022

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		20/01/2025	27/01/2025	Yes	No