

Central line placement in critically ill children: ultrasound versus landmark

Submission date 18/05/2026	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 12/06/2026	Overall study status Completed	☒ Statistical analysis plan ☒ Results
Last Edited 12/06/2026	Condition category Other	☐ Individual participant data

Plain English summary of protocol

Background and study aims

The placement of a central venous catheter (CVC) in critically ill children can be technically challenging and carries a risk of complications. The study compares two techniques for inserting a CVC into the internal jugular vein: the ultrasound-guided technique (TGUS) and the anatomical landmark technique (ALT), to determine which is more effective and safer.

Who can participate?

Children aged between 1 month and 15 years 11 months who are admitted to the Paediatric Intensive Care Unit (PICU) and require placement of a central venous catheter (CVC) in the internal jugular vein (IJV).

What does the study involve?

Interventions being compared:

TGUS (intervention): real-time ultrasound-guided central venous catheter (CVC) insertion using a linear transducer; Seldinger technique; catheters selected according to age/weight.

ALT (control): insertion using the anatomical landmarks technique (Trendelenburg position, identification of landmarks) using the Seldinger technique.

Procedure: a single placement attempt per patient (with up to 4 attempts permitted before declaring failure); sedation/analgesia according to protocol; confirmation of catheter position by chest X-ray or echocardiography.

Randomisation: 1:1 allocation by coin toss at the time of the procedure.

Blinding: single-blind study: outcome assessors and the statistical analyst remain blinded; operators are aware of the technique used.

Duration of follow-up: monitoring during hospitalisation and until catheter removal to detect complications.

What are the possible benefits and risks of participating?

Potential benefits: a better insertion technique (if TGUS proves to be superior) may increase the

likelihood of success in fewer attempts, reduce the duration of the procedure and minimise minor complications; it contributes to knowledge that may improve care for other children.

- Potential risks: complications associated with central venous catheter (CVC) placement, which may be immediate (e.g. arterial puncture, haematoma, pneumothorax), intermediate or delayed (e.g. catheter-related infection). The protocol includes safety measures, standardised procedures and imaging confirmation to minimise risks.

Where is the study run from?

The Paediatric Intensive Care Unit (PICU) at UMAE No. 48, the Gynaecology and Paediatrics Hospital, part of the Bajío National Medical Centre, in León, Guanajuato, Mexico.

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

June 2019 to August 2020.

Who is funding the study?

There was no external funding; the procedure was carried out using the hospital's own resources.

Who is the main contact?

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Contact information

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Study information

Scientific Title

Efficacy and safety of central venous catheter placement in the internal jugular vein, using the ultrasound-guided technique versus the anatomical landmark technique, in critically ill pediatric patients: Randomized clinical trial.

Acronym

Central Line In Children — Ultrasound vs Landmark

Study objectives

GENERAL OBJECTIVE

To assess the efficacy and safety of central venous catheter placement in the internal jugular vein using the ultrasound-guided technique versus the anatomical landmark technique in critically ill paediatric patients.

SPECIFIC OBJECTIVES

1. To establish the efficacy of central venous catheter placement using both techniques in critically ill paediatric patients.
2. To determine the safety of central venous catheter placement using both techniques in critically ill paediatric patients.
3. To compare whether there are differences in the efficacy and safety of central venous catheter placement using ultrasound-guided techniques versus anatomical landmark techniques in critically ill paediatric patients.

Ethics approval required

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Ethics approval(s)

Approved 20/06/2019, Comité Local De Investigación 1002 (COMBIOETICA 11 CEI 0062017103) (Paseo de los Insurgentes S/N, Los Paraísos, León, Guanajuato, 37328, Mexico; +1 52 477 7174800; investigaumae48@gmail.com), ref: R-2019-1002-028

Primary study design

Interventional

Allocation

Randomized controlled trial

Masking

Blinded (masking used)

Control

Active

Assignment

Parallel

Purpose

Treatment

Study type(s)

Health condition(s) or problem(s) studied

Central venous catheter placement in critically ill paediatric patients: ultrasound-guided versus anatomical landmark technique guided internal jugular vein catheterisation.

Interventions

A randomised, controlled, single-blind clinical trial in paediatric patients (aged 1 month to 15 years and 11 months) admitted to the Paediatric Intensive Care Unit (PICU) at UMAE No. 48, León, Mexico.

Interventions:

Ultrasound-guided central venous catheter (CVC) placement (TGUS): real-time puncture using a linear transducer (Philips 7500), Seldinger technique, sterile catheter and gel; catheter size according to age/weight (infants 4 Fr; 2–6 years 4–5 Fr; 6–10 years 5–7 Fr; >10 years 7 Fr).

Anatomical landmark technique placement (ALT, control): classic Seldinger approach using anatomical landmarks with the patient in the Trendelenburg position. The procedure consists of a single intervention per patient, performed under sedation/analgesia by standardised paediatric intensivists; the lumens were flushed with heparinised saline (100 IU/100 mL) according to local protocol. Failure was defined as failure to achieve cannulation after 4 attempts or the occurrence of a major complication; the final position of the catheter was confirmed by chest X-ray or echocardiography.

Randomisation: 1:1 allocation by coin toss at the time of the procedure; the study was single blind (operators were unblinded; outcome assessors and the statistical analyst were blinded via data coding).

Planned sample size 98 (49 per group); 73 patients recruited; the trial was stopped early on the recommendation of the independent committee following an interim analysis due to evidence of superior efficacy of TGUS.

Intervention Type

Procedure/Surgery

Primary outcome(s)

1. Effectiveness, based on the following three criteria: 1) successful placement of the central venous catheter; 2) fewer than two attempts required for placement; 3) a placement time of less than 20 minutes, and safety, according to the following criteria: 1) the absence of serious immediate complications; 2) the presence of two or fewer non-serious complications measured using the number of attempts on the data collection form, the duration of the procedure using a chronometer (from the first puncture to the final placement of the CVC), positioning via chest X-

ray or echocardiography (radiology/echocardiography report), and recording of immediate, intermediate and late complications from admission to the paediatric intensive care unit until removal of the central venous catheter, collected at one time point

2. Procedure-related complications, from central venous catheter placement until its removal measured using recording of immediate, intermediate, and late serious and non-serious complications until patient discharge, collected at one time point

Key secondary outcome(s)

Completion date

01/09/2020

Eligibility

Key inclusion criteria

1. Age: between 1 month and 15 years and 11 months at the time of the procedure
2. Admission: to be hospitalised in the Paediatric Intensive Care Unit (PICU) of UMAE No. 48, Hospital Gineco Pediatría
3. Clinical indication: requires placement of a central venous catheter (CVC) according to medical criteria
4. Gender: any gender (no restriction)

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

1 Months

Upper age limit

15 Years

Sex

All

Total final enrolment

73

Key exclusion criteria

1. Haematological malignancies with active coagulation disorders, defined by any of the following: prothrombin time greater than 18 seconds; activated partial thromboplastin time (aPTT) greater than 55 seconds. or platelet count less than $50 \times 10^9/L$.
2. Ongoing anticoagulant therapy
3. Malformation at the puncture site preventing the procedure
4. Legal guardian not providing informed consent
5. Incomplete medical records preventing the collection of essential data
6. Incomplete procedure data on the data collection form

7. Voluntary discharge of the patient before completion of the protocol
8. Withdrawal from the protocol by decision of the legal guardian
9. Transfer to another hospital unit preventing follow-up and evaluation of results

Date of first enrolment

12/09/2019

Date of final enrolment

05/08/2020

Locations

Countries of recruitment

Mexico

Sponsor information

Organisation

Mexican Social Security Institute

ROR

<https://ror.org/03xddgg98>

Funder(s)

Funder type**Funder Name**

Instituto Mexicano del Seguro Social

Alternative Name(s)

Mexican Social Security Institute, IMSS

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Mexico

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results	Child assent form		19/05/2026	No	No
Other files			11/06/2026	No	No
Participant information sheet			11/06/2026	No	Yes
Protocol file	within the protocol		11/06/2026	No	No
Statistical Analysis Plan			11/06/2026	No	No