COMPARISON OF THE EFFECTIVENESS OF ULTRASOUND-GUIDED TECHNIQUE AND INFRARED ILLUMINATION, COMPARED WITH THE STANDARD APPROACH TO PERIPHERAL VENOUS LINE PLACEMENT IN PEOPLE WITH DIFFICULT VENOUS ACCESS

REUSSIR-VVP

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STATISTICAL ANALYSIS PLAN

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LIST OF ABBREVIATIONS

A-DIVA	Adult Difficult Intravenous Access
CONSORT	Consolidated Standards Of Reporting Trials
CT	Computed Tomography
MRI	Magnetic Resonance Imaging
NRS	Numerical Rating Scale
PET	Positron Emission Tomography
PIVC	Peripheral Intravenous Catheter

1. Background and rationale of study

Peripheral intravenous catheter (PIVC) insertion is the most common invasive medical procedure worldwide. Improving the first-attempt success rate is a crucial issue for patients in terms of pain, anxiety, risk of extravasation, rapid access to care, and preservation of the patient-caregiver relationship; for caregivers in terms of self-confidence and autonomy; and for healthcare institutions in terms of reputation and societal cost.
According to estimates from 2021–2022, one in ten catheters used at the Groupement Hospitalier de Territoire de la Vienne is placed in the imaging department. In particular, CT scan services account for 66.3% of catheters ordered for imaging, due to the administration of iodinated contrast agents.
The literature describes two techniques for improving PIVC insertion success rates: ultrasound-guided insertion and infrared-assisted insertion. Their use appears to be effective only in patients with difficult venous access.
Furthermore, prediction of first-attempt success has been made possible by the A-DIVA clinical score. To date, no study has compared the efficacy of these two techniques in Europe, in imaging departments, or in relation to this clinical score. The objective of this study is to determine the most effective technique for successful PIVC insertion in patients with difficult venous access.

2. Study type

This is a monocentric, prospective, randomized, controlled, superiority, three-arm parallel-group (1:1:1 ratio) interventional trial with stratification by A-DIVA score (< 4 or higher) and operator experience (< 5 years or higher), conducted in patients with difficult venous access.

3. Objectives and endpoints

3.1 Primary objective

To compare the proportion of successful first-attempt peripheral venous catheterizations between the standard method (gold standard), ultrasound-guided technique, and infrared illumination technique in adult patients with difficult venous access.

3.2 Primary endpoint

Successful catheterization is defined as the placement of a functional catheter without immediate complications on the first skin puncture attempt.
The primary endpoint is binary and assessed by the healthcare provider at the first attempt.

3.3 Secondary objectives

1) To compare the proportion of successful peripheral venous catheterizations on the second attempt (if the first attempt fails) between the standard method (gold standard), ultrasound-guided technique, and infrared illumination technique in adult patients with difficult venous access.

2) To compare the total number of attempts among the three methods.

3) To compare the maximum pain experienced by the patient during the attempts (until successful PIVC placement or abandonment) among the three methods.

4) To compare overall patient satisfaction among the three methods.

5) To compare overall operator satisfaction among the three methods.

6) To compare the time required for catheterization—from the end of material preparation to successful catheterization—among the three methods.

7) To describe the fallback system in case of failure after two attempts (calling a colleague, changing technique or catheter, abandoning PIVC placement, or calling for central venous access).

8) To compare the catheter gauge used during the successful attempt among the three methods.

3.4 Secondary endpoints

1) Successful catheterization is defined as the placement of a functional catheter without immediate complications on the second skin puncture attempt (one puncture = one attempt).

2) Total number of skin punctures by a catheter.

3) Maximum pain will be assessed using a numerical rating scale (NRS) ranging from 0 to 10. The assessment will follow the question: "On a scale of 0 to 10, with 0 being no pain and 10 being the worst imaginable pain, how would you rate the maximum pain you felt during your IV insertion?"

4) Patient satisfaction will be measured using a NRS in response to the question: "On a scale of 0 to 10, with 0 being 'very dissatisfied' and 10 being 'completely satisfied,' how would you rate your overall satisfaction with your IV insertion?"

5) Operator satisfaction will be assessed on a NRS from 0 ("very dissatisfied") to 10 ("completely satisfied") in response to the question: "Are you satisfied with the placement of this catheter?"

6) Time will be recorded in minutes, starting after the operator prepares the PIVC tray. This includes vein localization, skin disinfection, tourniquet application, catheterization, connection to the infusion line, and securing with adhesive strips and occlusive dressing. If a failure occurs, the timer will not stop, and time will continue to be recorded until vascular access is achieved, including any alternative procedures used.

7) In case of failure, the need for a fallback will be recorded. The type of fallback will be recorded: calling another colleague, changing technique (standard, infrared, or ultrasound-guided), changing catheter gauge, abandoning PIVC placement, or calling for central venous access.

8) For each attempt, the catheter gauge used (in Gauge) will be recorded.

4. Inclusion criteria

- Patient aged 18 years or older
- Patient scheduled for a medical imaging appointment with a medical prescription requiring PIVC placement
- Patient with an A-DIVA score of 2 or higher
- Patient able and willing to comply with all study procedures
- Patient covered by a social security scheme or through a third party
- Patient who has provided written, free, and informed consent after receiving clear and comprehensive information about the study

5. Non-inclusion criteria

- Contraindications to PIVC placement:

  - Arm with an arteriovenous fistula
  - Limb with an orthopedic or vascular prosthesis
  - History of mastectomy, axillary lymph node dissection, or ipsilateral arm radiotherapy
  - Paralyzed limb
  - Presence of hematoma or wounds at the puncture site
  - Limb with phlebitis or an infectious focus
- Patient previously included in the study
- Individuals under enhanced protection, including:
  - Minors
  - Persons deprived of liberty by judicial or administrative decision
  - Persons residing in a healthcare or social institution
  - Pregnant or breastfeeding women
  - Adults under legal protection
  - Patients in emergency situations

6. Randomization details

Patients will be randomized in a 1:1:1 ratio to one of three groups:
- Control Arm: Standard method
- Experimental Arm 1: Ultrasound-guided method
- Experimental Arm 2: Infrared-assisted method

Randomization will be stratified by:
- Healthcare provider's experience with PIVC insertion: < 5 years or ≥ 5 years.
- A-DIVA score: score < 4 or score ≥ 4.

7. Sample size calculation

According to Yalçınlı's study[1], the proportion of successful first-attempt catheterizations is 62.2% for the standard method, 58.9% for the infrared-assisted technique, and 78.9% for the ultrasound-guided technique.
To detect an absolute difference of 20% in our study (78.9% versus 58.9%), with a two-sided alpha risk of 5% and a power of 80%, the required sample size is set as 83 patients per group (249 in total).
Accounting for 5% of randomized patients who may not be analyzable (missing primary endpoint data or post-randomization consent withdrawal), we plan to include 264 patients (88 per group).

8. Collected data

- Demographic data: Sex, age (in years).
- A-DIVA score.
- Type of imaging examination: CT scan, MRI, nuclear medicine, PET scan, X-ray.
- Healthcare provider's years of experience with PIVC insertion.
- Maximum pain (0–10) on the numerical rating scale (NRS).

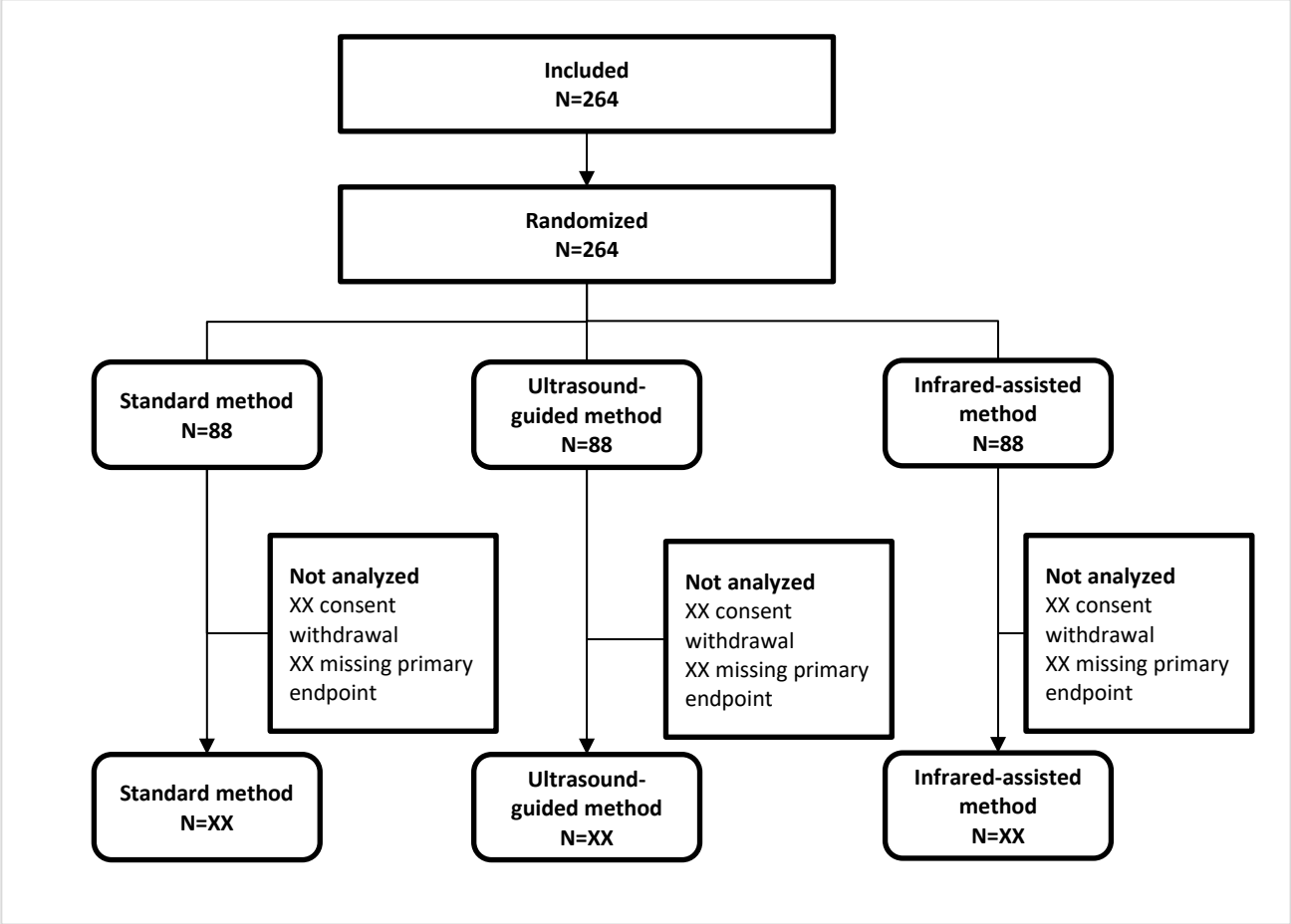
[1] Yalçınlı S, Akarca FK, Can Ö, Uz İ, Konakçı G. *Comparison of Standard Technique, Ultrasonography, and Near-Infrared Light in Difficult Peripheral Vascular Access: A Randomized Controlled Trial*. Prehospital Disaster Med. févr 2022;37(1):65-70.

- Overall satisfaction (0–10) of the patient and operator.
- Number of attempts.
- For each attempt:
  - Technique used
  - Catheter gauge
  - Success of the attempt (Yes/No)
  - Fallback method in case of failure (calling a colleague, changing technique, changing catheter gauge, abandoning PIVC insertion, or requesting central venous access)
- Time required for catheterization (in minutes).

9. Studied population

Patients wrongly included or lost to follow-up will be described. Protocol deviations will be documented and analyzed on a case-by-case basis.
Data analysis will be conducted using a modified intention-to-treat (mITT) approach, meaning all randomized patients will be analyzed according to their allocated treatment arm, except those who withdrew consent or lack primary endpoint data.

Figure 1. Flowchart



10. Description of baseline patient characteristics

Missing values will be reported. Categorical variables will be reported as frequencies (with associated percentages) for each level of the variable. Quantitative variables will be presented as mean (± standard deviation) or median (1st and 3rd quartiles) in cases of non-normal distribution.
A descriptive analysis will be conducted for each of the three groups. In accordance with CONSORT guidelines, the comparability of groups will not be tested for baseline characteristics[2].

Table 1. Description of patient's baseline characteristics

	Overall **N = 264**	**Standard method** **N=88**	**Ultrasound-guided method** **N=88**	**Infrared-assisted method** **N=88**
Age (in years)				
Gender				
Male				
Female				
History of difficult vascular access (yes/no)				
Type of imaging examination				
CT scan (TDM)				
MRI				
Nuclear medicine				
PET scan				
X-ray				
A-DIVA score (grades 2-5)				

11.Description of the endpoints

Endpoints will be described for each group and for the overall sample. Quantitative endpoints will be summarized using the mean and standard deviation. Qualitative endpoints will be summarized using frequencies and percentages for each level of the variable. The time required for catheterization will be summarized using the Kaplan-Meier estimator.

Table 2. Description of endpoints

Figure 2. Kaplan-Meier estimator for the time required for catheterization

12.Primary endpoint analysis

[2] de Boer MR, Waterlander WE, Kuijper LDJ, Steenhuis IHM, Twisk JWR. *Testing for baseline differences in randomized controlled trials: an unhealthy research behavior that is hard to eradicate*. Int J Behav Nutr Phys Act. 24 janv 2015;12:4.

The primary endpoint will be compared among the three groups using logistic regression, adjusted for the healthcare provider's experience with PIVC insertion (<5 years or ≥5 years) and the A-DIVA score (≥4 or <4).
The significance threshold will be set at 5%. The p-values and odds ratios (ORs) relative to the randomization group will be presented in *Table 2*.

13.Secondary endpoints analyses

The proportion of successful peripheral venous catheterizations on the second attempt will be compared among the three groups using logistic regression, adjusted for the A-DIVA score (≥4 or <4) and healthcare provider's experience with PIVC insertion (<5 years or ≥5 years). The p-values and odds ratios (ORs) relative to the randomization group will be presented in *Table 2*.
The time required for catheterization will be compared among the three groups using a Cox proportional hazards model, adjusted for the A-DIVA score and healthcare provider's experience with PIVC insertion. The p-values and hazard ratios (HRs) relative to the randomization group will be presented in *Table 2*.

The other quantitative endpoints (number of attempts, maximum pain, patient satisfaction, and healthcare provider satisfaction) will be compared among the three groups using a linear regression model, adjusted for the A-DIVA score and healthcare provider's experience with PIVC insertion. The p-values and regression coefficients relative to the randomization group will be presented in *Table 2*.

Subgroup analyses will be conducted to investigate the interaction between A-DIVA score (≥4 or <4) and the technique used (standard, ultrasound-guided, or infrared). These subgroup analyses will focus on the primary endpoint (successful peripheral venous catheterization on the first attempt) and the catheter gauge used during successful PIVC placement (secondary objective #8).

Analyses for secondary endpoints will be exploratory, and no adjustment for alpha inflation due to multiple testing will be applied. The significance threshold will be set at 5% for all analyses.

14.Methods for handling missing data

Missing data will be reported but no imputation will be performed.