STUDY PROTOCOL, STATISTICAL ANALYSIS PLAN & INFORMED CONSENT FORM

Diagnostic Accuracy and Operational Efficiency of Point-of-Care Ultrasound (POCUS) for Long Bone Fractures: A Brazilian Multicenter Study (POCUS-BONE BR)

Study acronym: **POCUS-BONE BR**

Document type	Study Protocol, Statistical Analysis Plan, and Informed Consent Form
NCT number	[NCT number: to be assigned]
Document date	08 July 2026
Protocol version	1.0
CAAE	99512126.7.1001.0068
Ethics approval	Approved on 08 July 2026 — Opinion (Parecer) No. 8.574.218, HC-FMUSP Research Ethics Committee (CEP); CONEP review not required
Study design	Observational, prospective, multicenter, cross-sectional diagnostic-accuracy study
Participating institutions	Hospital das Clínicas, University of São Paulo Medical School (HC-FMUSP); Hospital das Clínicas, Marília Medical School (HC-FAMEMA)
Principal Investigator	Emanuel Ayrton Balanga (HC-FMUSP)
Co-investigators	Hélio Penna Guimarães; Renato Tambelli; Renato Melo

English translation prepared for public posting on ClinicalTrials.gov. Translated from the original Portuguese protocol and consent form; no research-participant names are included.

Study Synopsis

Background. Long bone fractures show a rising global incidence, significantly affecting morbidity, mortality, and hospital costs. Although conventional radiography (X-ray) is the traditional gold standard, limitations such as ionizing radiation, transport logistics, and waiting time compromise efficiency in emergency departments. Point-of-Care Ultrasound (POCUS) emerges as a dynamic, portable, radiation-free alternative with promising accuracy in adults.

Primary objective. To determine the diagnostic accuracy (sensitivity, specificity, and predictive values) of POCUS in identifying long bone fractures in patients aged 18 years or older, compared with conventional radiography.

Secondary objectives. To measure the "door-to-diagnosis" time (ΔT); to assess reported pain (Visual Analog Scale, VAS) during the examinations; to quantify agreement between the bedside examiner and an Adjudication Committee (Kappa index); and to analyze whether examination order influences the outcomes.

Methods. This is an observational, prospective, multicenter, cross-sectional diagnostic-accuracy study conducted at HC-FMUSP and HC-FAMEMA. The convenience sample of 260 patients (adjusted for losses) will include adults with clinical suspicion of long bone fracture. The protocol uses the B.O.N.E.S. mnemonic for technical standardization. The reference standard is conventional radiography in two orthogonal views, interpreted by the service radiologist. A blinded Adjudication Committee, composed of an independent radiologist and emergency physician, reinterprets the radiography in cases of disagreement between POCUS and the initial report, acting as a quality control of the gold standard rather than as the reference standard itself. Examination order is recorded for memory-bias analysis. Data are collected via REDCap and analyzed in Stata or R, adopting a significance level of 5% ($\alpha = 0.05$).

Risks and benefits. Risks are minimal, limited to mild discomfort from transducer pressure over the injured area. Benefits include contributing to the validation of more agile diagnostic workflows, with potential reduction of hospital length of stay and unnecessary radiological exposure.

Keywords: Point-of-Care Ultrasonography; Bone Fractures; Diagnostic Imaging; Emergency Medicine; Diagnostic Accuracy.

1. Introduction

Bone fractures represent a critical challenge for global public health, showing a substantial increase in incidence and disease burden over recent decades (8). Between 1990 and 2019, the number of incident fracture cases worldwide grew by more than 33%, reaching approximately 178 million new cases annually (8). In the Brazilian setting, this impact is reflected in the profile of hospital admissions, notably femoral fractures, which carry high morbidity and mortality rates and rising costs for the health system (9).

Traditionally, conventional radiography (X-ray) has been the gold standard for the initial diagnosis of acute bone injuries (1). However, exclusive reliance on X-ray in emergency services imposes limitations, such as exposure to ionizing radiation — of

particular concern in pediatric populations — and delays in the care pathway owing to the need for patient transport and fixed radiological infrastructure (4). In this context, Point-of-Care Ultrasound (POCUS) emerges as a promising diagnostic alternative, offering portability, absence of radiation, and the capacity for dynamic bedside assessment (1,4).

Recent evidence supports that the diagnostic accuracy of ultrasound for fractures is comparable to that of radiography across several anatomical segments. Meta-analyses have demonstrated high sensitivity and specificity of POCUS for upper-extremity fractures, particularly the distal radius (5,7). In pediatric populations, ultrasound has proved an effective tool both for upper-limb injuries and for ankle trauma, enabling rapid and safe triage in the emergency department (2,3).

Despite the solid evidence in pediatrics, a paradigm shift is currently advocated that would extend the use of ultrasound to the adult population, integrating it routinely into the practice of emergency physicians, orthopedists, and general practitioners (4). Systematic reviews and narrative syntheses indicate that ultrasound not only detects cortical fractures accurately but can also identify injuries occult to X-ray, such as stress fractures and ligamentous avulsions (1,6). Thus, the validation of protocols that use ultrasound as a primary or adjunctive diagnostic tool is essential to optimize workflows and reduce unnecessary radiological exposure (4).

2. Rationale

2.1. Epidemiological Burden and Workflow Efficiency

The global incidence of bone fractures increased by more than 33% over the last three decades, reaching about 178 million new cases annually. At the national level, the profile of admissions for orthopedic trauma, such as femoral fractures, demonstrates a growing socioeconomic impact that demands more agile diagnostic strategies that are less dependent on centralized infrastructure. Exclusive reliance on conventional radiography (X-ray) imposes logistical bottlenecks, such as transporting patients in pain and waiting for image processing, which compromises door-to-diagnosis time in the emergency department.

2.2. Paradigm Shift and Patient Safety

Although X-ray is the traditional gold standard, the recent literature advocates a paradigm shift, suggesting that ultrasound (POCUS) should be integrated as a first-line tool in adults. The use of POCUS mitigates exposure to ionizing radiation — a relevant cumulative risk factor — and offers diagnostic accuracy comparable to radiography in detecting cortical discontinuities across several anatomical segments. Moreover, ultrasound shows superior sensitivity in identifying fractures occult to X-ray, such as avulsions and stress injuries, allowing more precise clinical management from the initial assessment.

2.3. Reduction of Suffering and Operational Feasibility

A critical differentiator of this study is the assessment of patient comfort. The positioning required to obtain orthogonal radiographic views is frequently painful and may exacerbate the injury. Because POCUS is a dynamic technique performed with the limb in a comfortable position, it has the potential to reduce the pain score during the diagnostic investigation.

2.4. Innovation in the Brazilian Context

The scarcity of Brazilian multicenter studies simultaneously evaluating accuracy, workflow time, and pain in the adult population (≥ 18 years) represents a knowledge gap that this project aims to fill. Validating POCUS as an immediate clinical decision-making tool in high-complexity teaching hospitals (HC-FMUSP and FAMEMA) will contribute to the rational use of resources and to the safety of care in high-turnover emergency settings.

3. Methods

3.1. Objectives

3.1.1. Primary Objective

To determine the diagnostic accuracy (sensitivity, specificity, positive and negative predictive values) of Point-of-Care Ultrasound (POCUS) in identifying long bone fractures compared with conventional radiography (gold standard) in patients aged 18 years or older.

3.1.2. Secondary Objectives

- To measure and compare the “door-to-diagnosis” time between POCUS and the definitive radiography report.
- To assess the pain intensity reported by the patient during both examinations using the Visual Analog Scale (VAS).
- To quantify inter-observer agreement across the different centers and levels of examiner experience (Kappa index).
- To assess the level of agreement between the bedside examiner and a blinded Adjudication Committee.
- To analyze the impact of examination order (X-ray first vs. POCUS first) on accuracy and time outcomes.

3.2. Data Collection Instrument

Data collection will be carried out via a structured electronic form on the REDCap platform, divided into four blocks:

- **Examiner and Patient Profile:** demographic data, time since graduation, and specialty.
- **POCUS Block:** ultrasonographic findings (presence of step-off, hematoma, or discontinuity) and recording of time T1.
- **Radiological Block:** independent radiologist report and recording of time T2.

- **Clinical Outcomes:** pain scale (VAS) for both procedures and final management adopted.

3.3. Statistical Analysis Plan

3.3.1. Design and Sampling

This is an observational, prospective, multicenter, cross-sectional diagnostic-accuracy study. The design is based on the paired comparison between the index test (POCUS) and the reference standard (conventional radiography), performed in the same patient during a single clinical encounter in the emergency department.

Population and study centers. The study will be conducted in the emergency services of the Hospital das Clínicas of the University of São Paulo Medical School (HC-FMUSP) and the Hospital das Clínicas of the Marília Medical School (HC-FAMEMA). The target population consists of patients seeking care for acute extremity trauma.

Eligibility criteria.

- **Inclusion criteria:** patients aged 18 years or older, presenting clinical suspicion of long bone fracture (pain, deformity, edema, or functional limitation), and agreeing to the Informed Consent Form (ICF).
- **Exclusion criteria:** patients with open trauma, hemodynamic instability (resuscitation priority), known previous fractures in the same bone segment, need for immediate surgical intervention, or refusal to participate.

Sampling strategy. Sampling will be non-probabilistic by convenience, owing to the nature of the emergency workflow and the need for the presence of a trained researcher to perform POCUS. Patients will be recruited consecutively during the periods when researchers are available at the participating centers.

Adjudication Committee and blinding. To ensure the rigor of the reference standard, an Adjudication Committee composed of specialists (emergency physicians and radiologists) will review, in a blinded manner:

- The POCUS images and technical findings, such as cortical discontinuity and subperiosteal hematoma.
- The conventional radiography images.
- The POCUS result will not be disclosed to the radiology team at the time of the initial examination, in order to maintain blinding.

Analysis of examination order. The order of execution (whether the patient underwent X-ray or POCUS first) will be recorded in REDCap. This variable will be used in subgroup analyses to identify potential biases from the examiner's prior knowledge.

3.3.2. Sample Size Determination

The target sample size was calculated to ensure the precision of the accuracy estimates, specifically the sensitivity of POCUS.

Calculation parameters. The standard formula for estimating proportions was used, assuming an expected sensitivity of 94% based on prior literature. A 95% confidence level ($Z = 1.96$) and a desired precision of ±5 percentage points were adopted.

- Confidence level: 95% (Z = 1.96)
- Expected sensitivity (P): 0.94
- Precision (L): 0.05
- Prevalence (prev): 0.45

$$n = [1.96^2 \cdot 0.94 \cdot (1 - 0.94)] / [0.05^2 \cdot 0.45] \approx \textbf{193 valid patients}$$

Sampling scenarios.

- **Minimum required sample:** with the parameters above, the formula yields a minimum of n ≈ 193 valid (evaluable) patients needed to estimate POCUS sensitivity with ±5 percentage-point precision.
- **Final recruitment target:** 260 patients (130 per center). Allowing for up to 20% incomplete data or post-collection exclusions, this yields approximately 208 evaluable patients — comfortably above the required minimum — while ensuring a balanced distribution between the two centers (HC-FMUSP and HC-FAMEMA).
- **Subgroup stability:** the balanced allocation across centers also supports sensitivity analyses and the external validity of the method across different institutional contexts.

3.3.3. Descriptive Analysis

Continuous variables (age, times, pain scale) will be expressed as mean and standard deviation or median and interquartile range, according to normality (Shapiro-Wilk test). Categorical variables will be presented as absolute frequencies and proportions with 95% confidence intervals.

Continuous variables (age, times, and pain scale). These variables can take any value within a range. The form of presentation depends on the symmetry of the data:

- **Normality test (Shapiro-Wilk):** before any calculation, this test is applied to verify whether the data follow a Gaussian (normal) distribution.
- **If the distribution is normal (symmetric):** data are expressed as mean and standard deviation.
- **If the distribution is not normal (asymmetric):** the median and interquartile range (IQR) are used.

Categorical variables (sex, fracture type, specialty). These variables represent qualitative groups or categories:

- **Absolute frequencies (n):** the raw count of occurrences in each category.
- **Proportions (%):** the percentage each category represents of the total sample.
- **95% confidence interval (95% CI).**

Subgroup presentation structure. In line with the multicenter design, the characteristics of participants and health services will be described in two ways: as the **total sample**, to provide the overall overview of the study; and **by subgroup**, comparing data between HC-FMUSP and HC-FAMEMA to identify whether the populations served at the two centers are comparable or present heterogeneities that need to be adjusted for in the final analysis.

3.3.4. Outcome and Between-Group Comparisons

Accuracy will be calculated using 2×2 contingency tables. The comparison of times and pain between methods will be performed using the paired Student's t-test or the Wilcoxon test. Agreement between POCUS and X-ray will be assessed using Cohen's Kappa coefficient.

Diagnostic accuracy (2×2 contingency tables).

- The primary outcome is analyzed as a binary variable (presence or absence of fracture), cross-tabulating the examiner's findings with the verdict of the Adjudication Committee.
- By cross-tabulating POCUS (index test) and X-ray (reference standard), we calculate sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV).
- Cohen's Kappa coefficient is used to compare the local examiner with the committee.
- These results are presented with their respective 95% confidence intervals (95% CI).

Comparison of times and pain (inferential tests).

- To compare paired continuous variables (the same patient undergoing both examinations), the paired Student's t-test is used if the data are normally distributed.
- If the distribution is non-normal (asymmetric), the Wilcoxon signed-rank test is used, ensuring precision in analyzing the reduction of door-to-diagnosis time and the pain scale.

Inter-observer agreement (Cohen's Kappa coefficient).

- To assess the reproducibility of the method across centers (HC-FMUSP and HC-FAMEMA) and across different levels of examiner experience, Cohen's Kappa coefficient is used.
- This analysis is essential to demonstrate that the benefit of POCUS is not dependent on a single operator but is a replicable technique across different hospital contexts.

Subgroup analyses and adjustments.

- Comparisons between subgroups (e.g., by hospital center or by long bone evaluated) are performed to identify heterogeneities in results.
- Where pertinent, regression models are used to estimate prevalence ratios adjusted for potential confounders, such as the physician's time since graduation or the structure of the health service.

3.3.5. Missing Data and Sensitivity Analyses

The reliability of the accuracy estimates depends on data completeness and on the absence of selection biases arising from losses to follow-up or recording failures. To mitigate these risks, the following protocols will be adopted:

- **Exclusion for incompleteness:** all cases with forms containing more than 20% missing data are excluded from the main analysis, ensuring that only records with sufficient informational density contribute to the overall estimates.
- **Absence of the gold standard:** patients who, for any reason, do not undergo conventional radiography (gold standard) after POCUS are mandatorily excluded,

since the absence of the reference test makes it impossible to calculate accuracy indicators (sensitivity and specificity).

- **Handling of missing data:** the extent and pattern of missing data are rigorously described in the final report. If relevant losses occur in key variables, multiple imputation is considered as a sensitivity analysis, assuming a plausible missingness mechanism, to validate whether the results of the main analysis remain stable.
- **Sensitivity analyses by anatomical segment:** stratified analyses are conducted to verify whether the diagnostic performance of POCUS varies significantly between upper- and lower-limb bones. This step is crucial to identify whether the anatomical conformation or the depth of the bone cortex influences the accuracy of the bedside method.

3.3.6. Software and Statistical Parameters

Analyses will be performed in Stata® or R software. A two-tailed significance level of 5% ($\alpha = 0.05$) will be adopted.

- **Analysis environment:** data are processed and analyzed using Stata® (institutional license) or R, chosen for their robustness in handling diagnostic-accuracy models and their capacity to process large volumes of data from multiple centers.
- **Statistical significance:** for all inferential analyses, a two-tailed significance level of 5% ($\alpha = 0.05$) is adopted; results with a p-value < 0.05 are considered statistically significant.
- **Precision estimates:** all accuracy indicators (sensitivity, specificity, and predictive values) and effect measures are reported with their respective 95% confidence intervals (95% CI).
- **Hypothesis testing:** two-tailed tests are applied, since the study considers the possibility that POCUS may perform either superiorly or inferiorly relative to the comparator standard across different subgroups or secondary outcomes.

3.4. Timeline

The schedule below corresponds to the study execution timeline registered on the Brazilian national research ethics platform (Plataforma Brasil).

Study stage	Start	End
Submission to Plataforma Brasil and coordinating-center Research Ethics Committee (HC-FMUSP)	16 Jun 2026	17 Jul 2026
Ethics review at HC-FMUSP and co-participating-center appraisal (HC-FAMEMA)	16 Jun 2026	08 Jul 2026
Study pre-registration (ReBEC)	17 Aug 2026	18 Sep 2026
Examiner training and certification	19 Sep 2026	19 Oct 2026
Data collection	19 Oct 2026	19 Aug 2027
Database lock and validation	20 Aug 2027	19 Sep 2027
Definitive statistical analysis	20 Sep 2027	20 Nov 2027

Study stage	Start	End
Thesis and manuscript writing / submission for publication	20 Nov 2027	20 Jan 2028

Schedule as registered on Plataforma Brasil (project version 1; submitted 24 June 2026). Total duration: approximately 19 months (June 2026 – January 2028). The coordinating-center Research Ethics Committee (HC-FMUSP) approved the study on 08 July 2026 (Opinion No. 8.574.218; CAAE 99512126.7.1001.0068), with no CONEP review required.

3.5. Budget

The POCUS-BONE BR study was designed to operate at low direct cost, leveraging the technological and clinical infrastructure already available at the partner institutions (HC-FMUSP and HC-FAMEMA), including ultrasound devices, radiology equipment, the institutional REDCap platform, and Stata® and R statistical software licenses. The table below presents three budget scenarios: Minimum, Medium, and Complete (to cover all possible scenarios). Values are in Brazilian reais (R$).

Category	Description	Minimum (R$)	Medium (R$)	Complete (R$)
1. Consumables	A4 paper, toner, binding, and printing of SOPs (ICFs, protocols, B.O.N.E.S. flowchart)	570	766	766
2. Support material	AZ folders, ID badges, envelopes, filing labels	484	484	484
3. Clinical supplies	Conductive ultrasound gel (beyond institutional use) and paper towels for transducer hygiene	112	202	202
4. Training and calibration	B.O.N.E.S. handbooks, training phantom, videoconferencing platform (6 months), workshop coffee breaks	—	720	1,570
5. Inter-center travel	Coach tickets SP↔Marília (4 trips × 2 researchers), lodging, meals, and local transport	—	1,800	2,600
6. Backup and storage	External 1 TB SSDs for encrypted local backup and a cloud plan (12 months) for POCUS images and REDCap exports	—	1,180	1,360
7. Office material	Pens, markers, sticky notes, clipboards, institutional stamps, and a project ID plate	188	278	418
8. Scientific publication	Language review and technical translation (EN) and Article Processing Charge (APC) for a Q1/Q2 open-access journal	—	—	11,600
9. Congress presentation	Registration (2 researchers), airfare, lodging (3 nights), meals, and A0 poster printing	—	—	6,640

Category	Description	Minimum (R$)	Medium (R$)	Complete (R$)
10. Technical reserve (10%)	Contingencies, exchange-rate variation (affects APC), fuel increases, equipment failures, and unmapped expenses	135	543	2,564
TOTAL ESTIMATED		**1,489**	**5,973**	**28,204**

Assumptions: 260 patients recruited (130 per center); 2 ICF copies per patient; total project duration of approximately 19 months (June 2026 – January 2028), with about 10 months of active data collection; HC-FMUSP ↔ FAMEMA distance of 443 km. Values in Brazilian reais (R$) based on 2025–2026 market references.

Operational observations.

- **Technological and clinical infrastructure:** the study uses ultrasound (POCUS) devices and conventional radiology infrastructure already available in the emergency services of HC-FMUSP and HC-FAMEMA, at no direct cost to the project.
- **Data management and analysis:** data collection uses the institutional REDCap® platform, and statistical processing uses Stata® or R, both already licensed by the participating institutions.
- **Human resources:** all stages — from patient inclusion to final analysis — are conducted by the responsible researchers, without hiring external services or paying specific stipends.
- **Absence of financial incentives:** in strict observance of ethical precepts, there is no remuneration or financial incentive for research participants or for the professionals involved in data collection.
- **Publication costs:** the Complete scenario foresees publication in an open-access journal with an Article Processing Charge (APC). If unavailable, dissemination is prioritized in journals without processing fees, or costs are sought through funding calls and institutional resources, without burdening protocol execution.
- **Technical reserve:** 10% of the subtotal is reserved for contingencies, exchange-rate variation (with direct impact on the APC), increased fuel costs, and unmapped expenses, in accordance with recommended practice in funding calls.

4. References

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Appendix A. Study Flowchart (Figure 1)

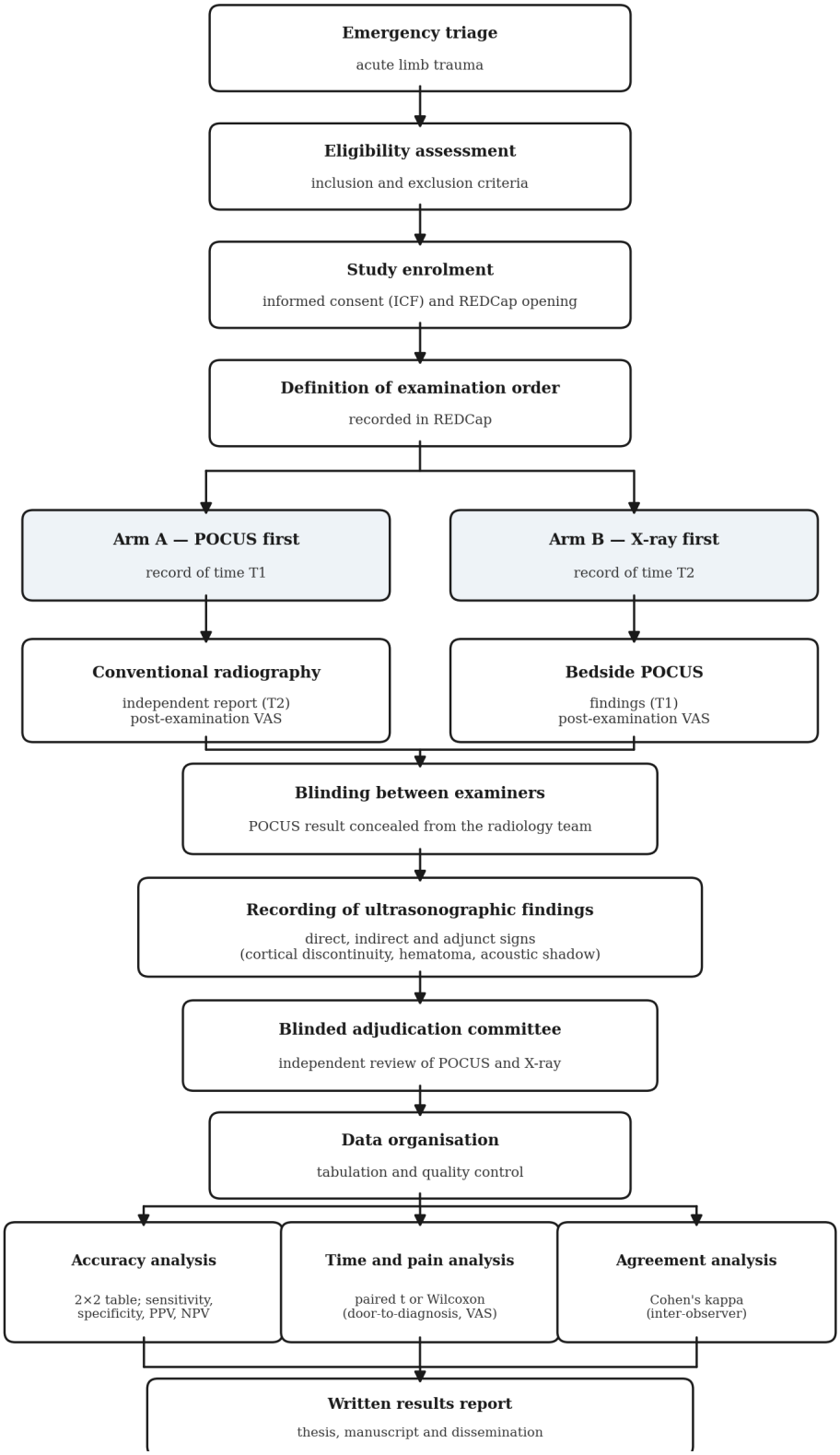


Figure 1. Conduct flowchart of the POCUS-BONE BR study.

Appendix B. POCUS-Specific Ultrasonographic Findings

Ultrasonographic finding	Technical description	Classification
Cortical discontinuity	Sharp interruption of the hyperechoic (white) line representing the bone surface.	Direct sign (pathognomonic)
Bone step-off	Vertical misalignment or “step” between two segments of the bone cortex.	Direct sign (displacement)
Subperiosteal hematoma	Anechoic (black) or hypoechoic collection just above the cortex, elevating the periosteum.	Strong indirect sign
Posterior acoustic shadowing	Dark shadow originating from the fracture cleft (where sound crosses the bone).	Adjunct sign
Comet-tail reverberation	Linear artifacts that arise specifically at the fracture site.	Adjunct sign
Continuous cortex	Smooth hyperechoic line, without interruptions, in two planes (longitudinal and transverse).	Negative POCUS

Appendix C. B.O.N.E.S. Protocol

- **B – Break (cortical discontinuity):** the sharp interruption of the hyperechoic line, which is the ultrasonographic signature of the normal bone surface. A direct and pathognomonic sign of fracture.
- **O – Off-set (bone step-off):** the vertical misalignment or “step” observed between two segments of the bone cortex, indicating displacement of the fracture fragments.
- **N – Near-fluid (subperiosteal hematoma):** an anechoic (black) or hypoechoic collection just above the cortex, elevating the periosteum. A strong indirect sign of acute bone injury.
- **E – Echo-shadow (posterior acoustic shadowing):** the dark shadow originating specifically at the fracture cleft, where sound waves cross the bone density. An adjunct diagnostic sign.
- **S – Spicule/Signs (adjunct signs):** linear artifacts such as comet-tail reverberation arising at the fracture site, aiding localization of the injury.

When the cortex is visualized as a smooth, continuous hyperechoic line in two planes (longitudinal and transverse), the examination is classified as **Negative POCUS**.

Appendix D. Standard Operating Procedure (SOP)

Title	Diagnostic Accuracy and Operational Efficiency of Point-of-Care Ultrasound (POCUS) for Long Bone Fractures: A Brazilian Multicenter Study (POCUS-BONE BR)
Code	SOP-TRAUMA-001
Centers	HC-FMUSP | HC-FAMEMA

1. Purpose

To standardize the ultrasound scanning technique for identifying cortical discontinuities in long bones (humerus, radius, ulna, femur, tibia, and fibula) in patients aged 18 years or older.

2. Equipment and Settings (Preset)

- **Transducer:** linear (7–12 MHz). In obese patients or for the proximal femur, use the convex probe (3–5 MHz).
- **Preset:** musculoskeletal (MSK) or soft tissue.
- **Focus:** adjusted to the depth of the bone cortex.
- **Gain:** adjusted so that the cortex is the most hyperechoic structure on the screen.

3. Examination Technique

- **Positioning:** keep the limb in the most comfortable position for the patient.
- **Identification of the pain point:** begin scanning at the zone of greatest reported tenderness or deformity.
- **Longitudinal scan (long axis):** slide the transducer longitudinally along the bone; the cortex should appear as a continuous hyperechoic line.
- **Transverse scan (short axis):** rotate the transducer 90° to confirm cortical steps or deviations in an orthogonal plane.
- **Contralateral comparison:** in case of doubt, scan the unaffected limb for anatomical comparison.

4. Diagnostic Criteria for Fracture

- **Cortical discontinuity:** abrupt interruption of the hyperechoic line.
- **Bone step-off:** vertical misalignment between the cortical ends.
- **Fracture hematoma:** anechoic or hypoechoic collection adjacent to the bone defect, frequently elevating the periosteum.

Appendix E. Informed Consent Form

Adult participants (≥ 18 years). Identifying fields are left blank for completion at the time of enrolment; no research-participant names are included.

Principal Investigator	Emanuel Ayrton Balanga — HC-FMUSP
Collaborators	Dr. Hélio Penna Guimarães — HC-FMUSP; Dr. Renato Tambelli — HC-FAMEMA

You are being invited to take part, as a volunteer, in a scientific research study. This document explains what will be done. Please read it carefully.

1. Why is this research being done?

We want to test whether the use of ultrasound (a device that uses sound waves to see inside the body, without radiation) is as accurate as X-ray for identifying fractures in the arms or legs. The goal is to validate a method that may be faster and that avoids unnecessary X-ray exposure in the future.

2. What will my participation involve?

If you agree to participate:

- You will receive all standard hospital care, including the X-ray requested by the emergency physician.
- The only difference: a physician from the research team will perform an ultrasound examination on the injured area. This examination lasts about 5 to 10 minutes and is performed at your bedside.
- The ultrasound results will later be compared with the X-ray results by the researchers.

3. What are the risks and discomforts?

Ultrasound is a safe examination and does not use radiation. The main risk is mild discomfort or pain at the injury site due to the contact of the ultrasound device needed to capture the image. If you feel pain, the examination will be stopped immediately.

4. What are the benefits?

There is no immediate direct benefit to you, since medical decisions will still be based on the X-ray. However, your participation will help science create protocols that make fracture diagnosis faster and safer for other patients in the future.

5. Confidentiality and no cost

Your identity will be kept in absolute confidence. Data and images will be identified only by codes. Your participation is entirely free of charge, and you will not receive payment for it. You may withdraw from participation at any time, without any harm to your treatment in the hospital.

6. Contacts

If you have questions, you may contact:

- **Principal Investigator:** Emanuel Ayrton Balanga — HC-FMUSP

- **Study contact:** Hélio Penna Guimarães — heliopg@yahoo.com.br
- **Researchers:** Dr. Renato Tambelli; Dr. Renato Melo
- **Research Ethics Committee (CEP), HC-FMUSP:** Rua Dr. Ovídio Pires de Campos, 225, 6th floor — Cerqueira César, São Paulo, SP, 05403-905 — phone (11) 2661-7585 — cappesq.adm@hc.fm.usp.br.

Consent of the participant (or legal guardian)

I, _____, ID (RG) _____, have understood the objectives and risks of the research and agree to participate voluntarily.

Place: _____ Date: _____ / _____ / 202____

_____ _____

Signature of the participant (or legal guardian)

Signature of the researcher