Title: **Effect of abdominal point-of-care ultrasound on correct preliminary diagnosis in adult emergency department patients with acute abdominal pain: protocol for a multicentre, parallel-group, randomized superiority trial**

Trial Protocol

Version 1

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The trial sponsor has no role in the design of the study and will not be involved in data collection, data analysis, interpretation of the results, or manuscript preparation. The principal investigator and the steering committee will have full access to the study data and will make the final decision regarding publication.

Composition and responsibilities

Principal investigator

Responsible for the overall scientific, ethical, and operational conduct of the trial, include the study protocol, obtaining regulatory and ethical approvals, trial registration, oversight of study conduct, statistical analysis, and dissemination of results.

Steering committee

Provides scientific oversight and guidance throughout the trial. Responsibilities include contributing to protocol development, reviewing major protocol amendments, and advising on data analysis, interpretation, and dissemination.

Endpoint adjudication committee

Responsible for the independent and blinded review of relevant clinical data and assignment of the final primary diagnosis. The committee's decision constitutes the reference standard for the study analyses.

Site investigators

Responsible for the conduct of the trial at their respective sites. Responsibilities include participant recruitment, supervision of informed consent procedures, ensuring data quality, and reporting protocol deviations or site-related issues.

Enrolling physician

Responsible for screening and enrolling participants, performing randomization, conducting Point of

Care Ultrasound (POCUS) examinations according to the study protocol, and obtaining informed consent for data collection.

Artificial intelligence

Artificial intelligence (Claude, Anthropic) has been used as a supportive tool in the preparation of the protocol, to review the protocol's structure and content against the SPIRIT checklist, for language editing and translation of text, and for the development of the statistical analysis plan. All AI-generated and AI-edited content was reviewed, verified, and approved by the author.

Open Science

Trial Registration

Protocol and statistical analysis plan

The full study protocol will be publicly available through publication of the protocol manuscript. The statistical analysis plan will be provided as supplementary material to the protocol publication.

Data sharing

Upon completion of the study, data will be anonymized, and only anonymized data will be used for analysis and potential data sharing. Access to data will require a methodologically sound research proposal approved by an independent scientific review committee and the steering committee and to relevant ethical and data protection regulations. Requests for data access can be made to the principal investigator.

Funding and conflicts of interest

Sources of funding

The study is funded by the Independent Research Fund Denmark (DKK 2,094,000), the Health Research Foundation of the Central Denmark Region (DKK 660,000), and the Engel-Friis Foundation (DKK 100,000). The funding provides direct financial support for the conduct of the study, including salary for the principal investigator.

The funders have no role in the design of the study; collection, management, analysis, or interpretation of the data, or the decision to submit the manuscript for publication.

All research funds awarded to the project are administered through a research account at Horsens Regional Hospital, held in the name of the sponsor. The principal investigator receives a PhD-funded salary covering the trial period. The rest of the study group receives no salary for their participation in the project. Neither the principal investigator, the sponsor, nor any other member of the project group has any financial affiliation with the funders beyond receipt of the awarded grants, and none have financial interests in manufacturers of ultrasound equipment or other commercial entities with potential interests in the outcome of the trial.

Conflict of interests

The principal investigator and members of the steering committee declare no financial or non-financial conflicts of interest related to this study.

Dissemination Policy

Results from the trial will be disseminated through peer-reviewed publications regardless of study findings. Reporting will follow the CONSORT guidelines for randomized controlled trials (1).

Only aggregated data will be published, and individual participants will not be identifiable. Trial results will be shared with participating sites and made available to participants upon request. A plain language summary may be prepared for dissemination to participants and the public.

All manuscripts will be reviewed and approved by the steering committee prior to submission. Authorship will follow the recommendations of the International Committee of Medical Journal Editors (ICMJE).

Introduction

Acute abdominal pain is one of the most common presentations in the emergency department (ED), accounting for 5-10% of all visits(2,3). Yet, despite its frequency, the diagnosis of abdominal pain remains challenging; symptoms are often overlapping and non-specific, and the range of potential differential diagnoses is wide(4). As a result, emergency physicians correctly identify the underlying diagnosis in only about 50% of the patients(5). This diagnostic uncertainty can result in wrong or delayed treatment, unnecessary imaging, and prolonged hospital stays. Hence, there is a need for additional tools to support timely diagnosis, and abdominal Point-of-care ultrasound (POCUS) could be part of the answer.

Abdominal POCUS is a rapid, bedside imaging tool performed by the treating clinician, as a supplement to the physical exam. It takes approximately 5 minutes to perform and may help diagnose both life-threatening conditions (e.g., abdominal aortic aneurysm(6,7), cholecystitis(8), small bowel obstruction(9)) and common causes of acute abdominal pain (gallstone disease(10), appendicitis(11), diverticulitis(12)). While ultrasound equipment is available in all Danish EDs and POCUS is included in the Danish national emergency medicine residency training programme, it is not yet routinely used in the diagnostic evaluation of patients with acute abdominal pain.

One possible explanation for this gap between availability and use is the limited evidence on whether abdominal POCUS actually improves clinical decision-making. Most existing studies on abdominal POCUS focus on the diagnostic accuracy for specific conditions, and only few studies have investigated, whether abdominal POCUS help clinicians make more accurate diagnoses. The results from these studies are mixed. Studies by Lindelius(5), Jang(13), and Durgun(14) suggest improved diagnostic precision or changes in treatment plans when POCUS is used. However, a RCT by Brau et al.(15), found no significant improvement in diagnostic precision when the physicians used POCUS. Thus, despite promising signals, robust evidence on the clinical impact of POCUS in acute abdominal pain remains lacking, which our study aims to address.

Objectives and hypothesis

The aim of this study is to determine whether the addition of abdominal POCUS to the standard examination of patients with acute abdominal pain in the ED, increases the proportion of patients with a correct preliminary diagnosis, using a final adjudicated diagnosis as the reference standard. As abdominal

POCUS is not yet part of standard practice in Danish EDs, standard clinical assessment without PoCUS was chosen as the comparator, reflecting current usual care. We hypothesize that the group using abdominal PoCUS will achieve a higher proportion of correct preliminary diagnoses compared with standard clinical examination alone.

Methods

Study design

This is a multi-centre, randomized, superiority, open-label, controlled trial with two parallel groups. The reporting of this protocol follows the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) guidelines(16). Patients or the public were not involved in the design, conduct, or reporting of this trial.

We will include patients with acute abdominal pain, presenting in the ED. Patients will be randomly allocated in a 1:1 ratio to one of the two arms of the study. The study procedure to be performed will be either:

1) Standard examination
2) Standard examination + abdominal POCUS examination

After assessment of the patient, the enrolling physician will document a preliminary diagnosis. After minimum one month, an adjudication committee will assign a final diagnosis based on available clinical information from the patient chart. This adjudicated diagnosis will serve as the reference standard.

Study setting and site organization

Physicians and patients from multiple EDs will be included, university hospitals as well as regional hospitals. The following EDs are expected to include patients: Horsens, Goedstrup, Aarhus, Holbæk, Esbjerg and Viborg. Each site appoints a local investigator to coordinate recruitment and ensure protocol adherence. Inclusion is planned over 13 months (October 2026–November 2027). The principal investigator (the PhD student) will oversee trial operations, ensure data quality, and maintain contact with sites. Data are entered into a shared REDCap® database.

Eligibility criteria

Eligibility criteria patients

Inclusion Criteria

1. ED contact.
2. Age ≥18 years.
3. Non-traumatic, acute abdominal pain, defined as symptom onset ≤7 days prior to presentation, as chief complaint.
4. Ability to provide written informed consent, as judged by the enrolling physician, and to communicate in Danish or English.

Exclusion Criteria

1. Prior enrollment in the trial.
2. Patients in whom the cause of the current abdominal pain is considered known at the time of enrolment (previously diagnosed condition explaining the current symptoms, e.g. known symptomatic gallstone disease).
3. Prior physician assessment of the presenting abdominal complaint during the current ED visit.
4. Prior ED assessment or received an abdominal ultrasound or CT scan for the same complaint, within the preceding 7 days.
5. Chronic abdominal pain, defined as abdominal pain persisting or recurring for ≥3 months(17), where the current episode represents an exacerbation of the chronic condition.
6. Patients requiring immediate critical care or rapid-response team activation.

Eligibility criteria enrolling physicians

All enrolling physicians must be either emergency medicine specialists or residents, certified in abdominal POCUS, and must have performed a minimum of 50 prior abdominal POCUS examinations. Certification must have been obtained through the POCUS course that is part of the Danish emergency medicine residency programme, or an equivalent course.

Eligibility criteria adjudication committee

Adjudication committee members must be board-certified specialists in emergency medicine or abdominal surgery. Adjudicators must not be enrolling physicians in the trial.

Eligibility criteria POCUS expert panel

Image quality and diagnostic agreement will be assessed by a PoCUS expert panel, consisting of physicians independent of both the enrolling physicians and the main study adjudication committee, with a minimum of 5 years of experience in abdominal PoCUS.

Intervention and comparator

Standard clinical examination + Abdominal POCUS group (Intervention)

Participants in the intervention group will undergo an abdominal POCUS examination in addition to the standard clinical examination. The scan will be performed by the enrolling physician as part of the initial bedside assessment, with timing, workflow, equipment, transducer, and preset left to the physician's discretion. The examination typically takes 5–10 minutes, and findings may guide further diagnostics or treatment, again at the physician's discretion.

Abdominal PoCUS protocol

The scans performed will be a standardized protocol (see Figure 1). This protocol was developed by the steering committee and covers conditions in the ED that are common or critical, accessible to abdominal PoCUS, and supported by solid evidence on diagnostic accuracy. Protocol completion is defined as the attempted assessment and documentation of all predefined components, including cases where visualization is not possible.

Physicians are encouraged to follow the protocol. However, any additional findings observed during the scan, or any additional structures scanned based on the physician's own training and clinical suspicion, must be documented.

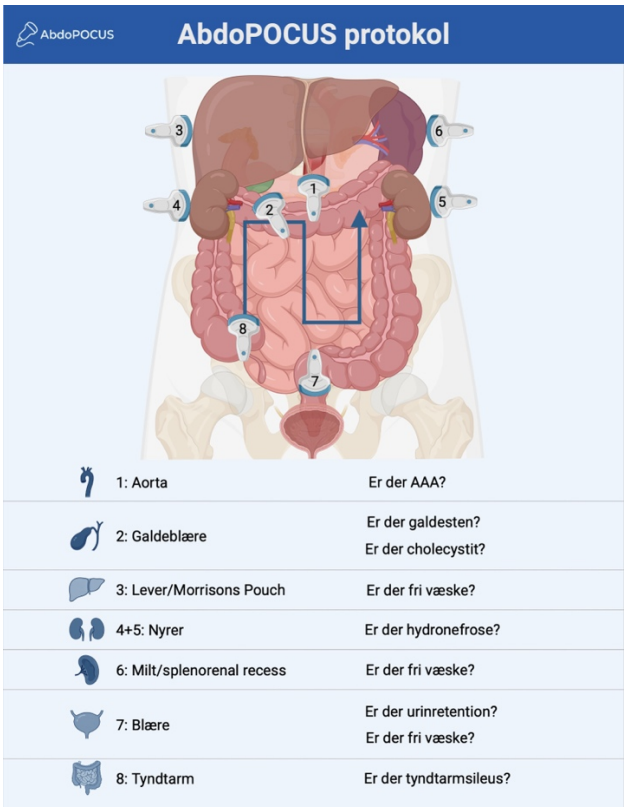

Figure 1

Standard examination group (Control)

Participants in the control group will receive a standard physical examination in line with local guidelines.

Abdominal POCUS cannot be performed during the ED stay in this group. However, other PoCUS modalities (e.g. lung or cardiac ultrasound) or ultrasound by a radiologist may still be applied if clinically indicated.

Outcomes

Primary outcome

The primary outcome is the correct preliminary diagnosis, defined as agreement between the enrolling physician's preliminary diagnosis and the final adjudicated diagnosis.

Secondary outcomes

1. **Inclusion of correct diagnosis in the differential diagnosis**: The proportion of patients in whom the final adjudicated diagnosis is included in the list of differential diagnoses recorded by the physician after the initial clinical assessment.
2. **Appropriateness of next diagnostic/therapeutic step:** The proportion of patients in whom the subsequent diagnostic or therapeutic step is concordant with the final diagnosis.
3. **ED length of stay**: Time from randomization to physical departure from the ED.
4. **ED re-attendance**: Re-attendance to the ED within 7 and 30 days following the index visit.
5. **Number of additional diagnostic tests:** The number of additional diagnostic tests performed after the initial clinical assessment during the index ED visit.
6. **Physician-reported diagnostic confidence:** Measured using a visual analogue scale from 0-100 following the initial clinical assessment.

Sub-study: Physician expectation

A pre-specified sub-study will examine whether the diagnostic benefit of PoCUS is greater in patients for whom the enrolling physician anticipates a diagnostic contribution from ultrasound. At the point of randomization, prior to opening the randomization envelope, the enrolling physician will answer the question on a dedicated paper form; “Do you expect that an abdominal PoCUS examination would contribute to the diagnostic reasoning in this patient?” (yes/no). The form is completed before group allocation is revealed, in both trial arms, and is subsequently transcribed to the trial database.

Within the intervention group only, the proportion of correct preliminary diagnoses will be compared between patients for whom the physician answered "yes" and those for whom the physician answered "no". We hypothesize that diagnostic accuracy will be higher among patients for whom the physician expected a diagnostic contribution from POCUS. This analysis is exploratory and hypothesis-generating and is not powered for formal statistical testing.

Diagnostic survey

The enrolling physician will complete a diagnostic survey in REDCap® following the standard clinical examination with or without abdominal POCUS. From a list of predefined diagnostic categories, based on the ICD-10 classification, the physician has to report their primary preliminary diagnosis, and up to three

differential diagnoses. Confidence in the preliminary diagnosis will be rated on a 0–100 visual analogue scale.

Adjudication

Each case will be independently reviewed by two adjudicators from different emergency medicine or abdominal surgery. Each patient will be followed for 30 days after the index admission. In case of disagreement, a third adjudicator will review the case, and consensus will be reached through discussion.

A single final diagnosis will be assigned for each patient, according to a structured adjudication protocol corresponding to those available in the enrolling physicians' diagnostic survey. In addition, adjudicators will assess whether the subsequent diagnostic or therapeutic management was appropriate according to local hospital guidelines.

Harms

The abdominal POCUS examination is brief and is not expected to delay diagnostic workup or initiation of treatment. It is non-invasive and involves no exposure to ionizing radiation. Ultrasound users should always be aware of the thermal and mechanical indexes, but no additional precautions beyond standard clinical practice are required for abdominal ultrasound in this patient population(18).

Potential indirect risks associated with adding abdominal POCUS to the standard examination include false-positive findings, which may lead to additional diagnostic procedures, and false-negative results, which could delay further diagnostic workup. However, available evidence does not indicate that using abdominal POCUS increases downstream imaging or diagnostic interventions. Brau et al. showed, the number of additional imaging examinations was similar between patients assessed with POCUS and those receiving standard care, as well as the number of diagnostic procedures(15).

In settings where enrolling physicians regularly use abdominal POCUS as part of their routine clinical practice, allocation to the control group may be seen as a limitation of standard care. However, in all cases, the enrolling physician retains full clinical responsibility and may stop or alter the allocated intervention if needed due to clinical deterioration or patient safety concerns.

As no specific harms are anticipated from the abdominal POCUS examination itself, harms related to trial participation will be assessed non-systematically through routine review of the patient's clinical course and documented in the trial database if observed.

Participant timeline

Eligibility will be assessed by the ED personal and the enrolling physician based on triage and primary complaint. Patients presenting with abdominal pain as the primary complaint will be approached by the enrolling physician, who will obtain a focused history. Eligible patients will receive oral and written information about the study and be given sufficient time to consider participation.

Upon giving consent, the enrolling physician completes a “Physician expectation” assessment form (See “sub-group analysis”) and opens the randomization envelope. The patient is then examined according to allocation. The enrolling physician will then complete a brief electronic diagnostic survey to record the preliminary diagnosis.

After a 30-day follow-up period, an adjudication committee will determine the final diagnosis based on a review of the patient’s clinical course and available data.

Sample size calculation

Based on results from the existing literature, about 50% of patients receive a correct preliminary diagnosis from clinical assessment alone(19,20). Lindelius et al. demonstrated an absolute improvement of 8 percentage points (57% to 65%) with surgeon-performed ultrasound in patients with acute abdominal pain. The more recent randomized trial by Brau et al. assumed a 17-percentage point improvement in their power calculation but found no significant effect and concluded that their assumed effect size represented an overestimation. Taking these findings together, a clinically relevant improvement in the preliminary diagnosis using POCUS was estimated at 13 percentage points, corresponding to an increase to 63% in the intervention group. This corresponds to one additional correct preliminary diagnosis for every eight patients assessed, which was considered the minimum clinically meaningful effect at the bedside. Smaller differences were considered less likely to influence clinical decision-making in the ED setting and were therefore not used for sample size estimation. The sample size is calculated using a two-sided test to compare two independent proportions with a significance level of 0.05 and 80% power,

including a 10% margin to accommodate patient dropout. This results in a final sample size of 254 patients per group, totaling 508 patients.

Recruitment

Inclusion will take place from October 2026 to November 2027. The total study period is expected to run until August 2028. A conservative recruitment estimate assumes that each participating site will have two physicians actively enrolling patients, resulting in a total of 12 enrolling physicians across six sites. If each physician enrolls one patient every 10 days on average, the total recruitment period required to reach 508 patients would be approximately 424 days. Based on these conservative assumptions, completion of enrollment by November 2027 is considered feasible. Recruitment rates will be monitored centrally throughout the inclusion period.

No intervention-related actions will take place before patients have signed an informed consent form. Patients will be screened for eligibility 24/7 using a convenience sample whenever enrolling physicians are present in the department. Potential participants will be identified based on triage information and presenting complaints prior to any physician-led clinical assessment. Oral and written study information will be provided by the enrolling physician prior to any study procedures. Participants may withdraw consent at any time without consequences for their clinical care. In the event of withdrawal, no further data will be collected; however, data collected prior to withdrawal will be retained and analyzed in accordance with Danish legislation(21).

Randomization

Randomization will occur after the enrolling physician has obtained the patient's medical history and prior to the physical examination. The allocation sequence will be generated in R (R Foundation for Statistical Computing, Vienna, Austria) using the blockrand function, with a 1:1 allocation ratio and variable block sizes of 2, 4, and 6 within each site. A separate sequence will be generated for each participating site, ensuring balanced allocation between the intervention and control arms within each center

Allocation concealment mechanism

A researcher not involved in patient enrolment will prepare sequentially numbered, opaque, sealed envelopes containing the allocation according to this sequence. The envelopes will be stored securely to ensure allocation concealment. The randomization sequence is stored in a restricted-access folder,

accessible only to the principal investigator, within a secure data environment, and enrolling physicians have no access to it at any point before opening the sealed envelope.Blinding

Neither the patient nor the enrolling physician will be blinded to group allocation because of the nature of the intervention. However, adjudicators will be blinded. Studypersonal not enrolling patients will udtrække journaldata fra dag 0 og 30 dage frem og blinde I PDF form. Såfremt adjudicators efterspørger yderligere journaldata frem eller bagud I tid, vil dette blive givet.

Blinding

Neither the patient nor the enrolling physician will be blinded to group allocation, due to the nature of the intervention. Adjudicators, however, will be blinded to allocation throughout the trial, and no unblinding is planned under any circumstances. To further safeguard blinding, adjudicators will not adjudicate cases in which they were personally involved in the patient's clinical care.

Study personnel not involved in patient enrolment will extract medical record data from day 0 to day 30 and prepare blinded PDF copies for adjudicator review. In addition to explicit allocation information, indirect indicators of group allocation, including any mention of the ultrasound examination in clinical notes, ultrasound-related procedure or billing codes, and differences in note length or structure between the two study arms, will be removed prior to review. If adjudicators request additional medical record data from an earlier or later time point, this will be provided in the same blinded format.

The POCUS expert panel assessing cine loop recordings for inter-rater agreement will likewise be blinded to the scanning physician's original findings.

Data collection methods

Group allocation, preliminary diagnosis, POCUS findings, and diagnostic confidence are entered prospectively into REDCap by the enrolling physician immediately after initial evaluation. Physician characteristics are collected at baseline using a separate questionnaire.

Baseline demographic and clinical variables are obtained from the electronic medical record by trained study personnel or the primary investigator and are used to describe the study population and adjust statistical analyses. Follow-up data are extracted from the electronic medical record ≥30 days after

discharge by trained study personnel or the primary investigator. Final diagnoses and appropriateness of management are decided by the adjudicators and put into REDCap.

All variables, data sources, timing, and intended analytical use are detailed in Table 1.

Cine loops

Ultrasound cine-loops are documented for all protocolized acoustic windows. Indeterminate or missed views that are not saved in cine-loops will be documented, both in the diagnostic survey and in the electronic patient record.

Image quality will be assessed in a random sample of 10% of all scans, rated by the PoCUS expert panel on a 5-point scale (1–5) reflecting the overall diagnostic quality of the acquired images. To assess inter-rater agreement, a subset of cine loop recordings will be compiled and reviewed by the POCUS expert panel, blinded to the scanning physician's original findings. For each recording, the panel will independently assess whether specific predefined findings are present. Agreement between the panel's assessment and the scanning physician's original findings will be quantified using Cohen's kappa.

Ultrasound cine-loops will be saved on the ultrasound device under the patient’s study ID, ensuring pseudonymization. During site visits, the principal investigator will transfer cine-loops from the ultrasound device to a hardware-encrypted USB drive and subsequently upload them to a secure storage location managed by the Central Denmark Region.

Diagnostic survey

The enrolling physicians will provide their preliminary diagnosis, along with up to three differential diagnoses. The predefined diagnostic categories from which physicians can choose were developed a priori based on the ICD-10 classification system, including the most common conditions and diseases that can present with abdominal pain in the ED.

The ultrasound examination will be documented in the POCUS group, with systematic recording of all protocol components and confirmation of whether the complete protocol was performed.

Contextual variables will include the availability of laboratory results. The survey will additionally include questions on anticipated management: "Do you think the patient will need to be admitted?", "Do you

think the patient will need a surgical, gyneological or urological consult?", "Do you think the patient will need an operation?", and "Do you think the patient will need another intervention?"

Adjudication

The reference standard (the final diagnosis) will be established by an independent adjudication committee, in which each case is independently reviewed by two adjudicators from different specialties (emergency medicine, radiology, or abdominal surgery); disagreements are resolved by a third adjudicator. This duplicate-review process is intended to promote data quality and reduce misclassification. All adjudicators will receive standardized training in the adjudication procedure. Prior to initiation of the adjudication process, a kick-off meeting will be held (online if necessary) to ensure alignment of the procedure.

Table 1

Variable category	Variables	Data source	Recorded by	Timing	Purpose
Trial data	Group allocation (intervention/control)	Paper form, transcribed to REDCap®	Enrolling physician	Initial assessment	Baseline description, analysis stratification
Diagnostic reasoning	Differential diagnoses, preliminary diagnosis	REDCap®	Enrolling physician	Initial assessment	Primary outcome
Diagnostic confidence	0–100	REDCap®	Enrolling physician	Initial assessment	Secondary outcome
PoCUS findings	Ultrasound findings, protocol completion	REDCap®	Enrolling physician	Initial assessment	Intervention data
Clinical presentation	Pain localization	REDCap®	Enrolling physician	Initial assessment	Baseline description, table 1, subgroup
Clinical variable	Time of assessment	REDCap®	Enrolling physician	Initial assessment	Covariate
Clinical variable	Lab availability	REDCap®	Enrolling physician	Initial assessment	Subgroup analyses
Physician characteristics	Experience, ultrasound competence	REDCap®, baseline questionnaire	Enrolling physician	At study start	Subgroup analyses
Follow-up clinical data	Imaging	Electronic medical record	Study personnel (data extraction)	Follow-up	Dataset for analysis
Follow-up clinical data	Laboratory results	Electronic medical record	Study personnel (data extraction)	Follow-up	Dataset for analysis
Follow-up clinical data	Microbiological results	Electronic medical record	Study personnel (data extraction)	Follow-up	Dataset for analysis

Follow-up clinical data	Pathology results	Electronic medical record	Study personnel (data extraction)	Follow-up	Dataset for analysis
Demographics	Age, sex	Electronic medical record	Study personnel	Follow-up	Baseline description, table 1, subgroup
Clinical variable	Body mass index	Electronic medical record	Study personnel (data extraction)	Follow-up	Baseline description, table 1, subgroup
Comorbidity	Key conditions	Electronic medical record	Study personnel	Follow-up	Baseline description, table 1
Lifestyle	Smoking status, alcohol use	Electronic medical record	Study personnel	Follow-up	Baseline description, table 1
Vital signs	Blood pressure, heart rate, temperature	Electronic medical record	Study personnel	Follow-up	Baseline description, table 1
Pain	Pain localisation	Electronic medical record	Study personnel	Follow-up	Baseline description, table 1
Follow-up clinical data	Treatment	Electronic medical record	Study personnel (data extraction)	Follow-up	Adjudication basis, secondary analyses
Final diagnosis	Adjudicated diagnosis	Electronic medical record	Adjudicators	≥30 days follow-up	Reference standard
Appropriateness	Appropriateness of inintial management	Electronic medical record	Adjudicators	≥30 days follow-up	Secondary outcome

Data monitoring

The abdominal PoCUS exam is considered a minimal-risk intervention. Given the low-risk nature of the study and the absence of investigational medicinal products or invasive procedures, no formal data safety monitoring board or interim analyses of outcome data are planned.

The study is conducted in accordance with the principles of Good Clinical Practice. As the trial involves the use of CE-marked diagnostic ultrasound equipment within its intended purpose and does not include additional risk beyond standard care, no specific external GCP monitoring is required.

International sites

Non-Danish sites can participate on the same terms as Danish sites and physicians. Local legislation must be followed, and local ethics committees consulted. Data will be kept and managed under local site facilities and data collection methods may be altered according to feasibility and available sources. Few secondary or tertiary outcomes may also be omitted if data are not producible or clinical practice is affected.

Statistical analysis plan

Primary analysis

The primary outcome is correct preliminary diagnosis, defined as agreement between the enrolling physician's preliminary diagnosis and the final adjudicated diagnosis. The outcome will be analyzed as a binary variable (correct vs incorrect).

The primary analysis will follow the intention-to-treat principle, including all randomized participants analyzed according to allocated group.

Each physician's clinical and ultrasound experience will be recorded in a baseline questionnaire. This information will be used in pre-defined subgroup analyses.

The effect of abdominal PoCUS plus standard clinical examination compared with standard clinical examination alone will be estimated using a generalized linear model with binomial distribution and identity link, accounting for clustering at the level of the enrolling physician. Results will be reported as absolute risk differences with 95% confidence intervals(22). A two-sided significance level of 0.05 will be applied. Superiority will be concluded if the 95% confidence interval for the absolute risk difference does not include zero.

Secondary analysis

All analyses will account for clustering at the level of the enrolling physician. Randomization ensures comparability between groups but does not ensure independence between observations. Because multiple patients are assessed by the same physician, outcomes may be correlated, and clustering must therefore be accounted for.

Inclusion of the correct diagnosis in the differential diagnosis, the appropriateness of the next diagnostic or therapeutic step and ED re-attendance at 7 and 30 days will be analyzed as binary outcomes using generalized linear models with binomial distribution. Results will be reported as absolute risk differences with 95% confidence intervals.

ED length of stay will be analyzed as a continuous outcome. Given the expected right-skewed distribution, analyses will be performed using log-transformed values. Results will be reported as mean differences or ratios, as appropriate, with 95% confidence intervals.

The number of additional diagnostic tests will be analyzed as count data. Depending on data distribution, comparisons between groups will be performed using either Poisson or negative binomial regression models, with results reported as incidence rate ratios (IRRs) with 95% confidence intervals (CIs).

Physician-reported diagnostic confidence (0–100 visual analogue scale) will be analyzed as a continuous outcome using linear regression, with results reported as mean differences and 95% CIs.

All models will be adjusted for prespecified covariates where relevant. Model assumptions will be assessed, and appropriate alternative methods will be applied if violations are detected.

Subgroup analyses

The trial is not powered to detect subgroup effects; therefore, all subgroup analyses are prespecified as exploratory and hypothesis-generating. Subgroup analyses will assess potential effect modification according to: (1) clinical presentation (e.g. right upper quadrant pain, lower left abdominal pain, diffuse abdominal pain); (2) physician ultrasound competence; (3) availability of laboratory results at the time of the preliminary diagnosis; and (4) body mass index.

Missing data

Missing data will be reported for all baseline characteristics and outcomes. Baseline characteristics will be compared between participants with complete and incomplete primary outcome data to evaluate potential systematic differences.

The primary analysis will be conducted using complete case analysis. The extent and patterns of missing data will be reported. If more than 5% of data are missing, multiple imputation by chained equations will be performed as a sensitivity analysis. The imputation model will include relevant baseline variables and outcomes, and missingness will be assumed to be missing at random. However, we anticipate minimal missing data for the primary outcome. All imputed analyses will be conducted as sensitivity analyses, with primary inference based on complete-case results.

Sensitivity analysis

Sensitivity analyses will be performed to assess the robustness of the findings to key assumptions and analytical choices. For the primary outcome, analyses will be repeated using multiple imputation if more than 5% of data are missing. In addition, alternative modelling approaches will be explored where

relevant, including models with different distributional assumptions for continuous outcomes and alternative approaches to handling clustering. Results from sensitivity analyses will be compared with the primary analysis to evaluate the consistency of findings.

Ethical considerations

This study has been approved by the Regional komité for Region Midtjylland, reference number 1-10-72-73-26, approved on 21/07-2026. As the trial is coordinated by a principal investigator affiliated with Region Midtjylland, this approval covers all participating sites across the three involved regions, in accordance with Danish procedures for multicentre trials.

Risk–benefit assessment

The intervention consists of a brief, non-invasive abdominal ultrasound examination performed as part of the initial clinical assessment. All participants receive at least standard ED care, and the enrolling physician retains full clinical responsibility throughout. Only clinically stable patients capable of providing informed consent will be approached for participation.

Potential risks include false-positive or false-negative ultrasound findings; however, available evidence does not indicate increased downstream imaging or harm associated with abdominal PoCUS.

Given the minimal risks and the potential to improve diagnostic accuracy and patient flow, the anticipated benefits of conducting the study outweigh the potential harms.

Confidentiality

The study will comply with the General Data Protection Regulation and the Danish Data Protection Act. All required data protection approvals, registrations, and institutional agreements will be obtained prior to study initiation.

Relevant clinical variables will be identified in the participant's electronic medical record and entered manually into the study database (REDCap®) by the principal investigator or designated research personnel. Each participant is identified in REDCap® by a unique study ID rather than personal identifiers (CPR number). A separate, secure key linking study IDs to personal identifiers is maintained on a password-protected institutional drive accessible only to the principal investigator and designated study personnel. REDCap® is hosted on an institutional server with restricted, role-based access.

Ultrasound cine-loops are saved on the ultrasound device under the participant's study ID. Files are transferred to secure institutional storage using a hardware-encrypted USB drive and subsequently deleted from both the ultrasound device and the USB drive. The key linking study IDs to personal identifiers is not transported together with the cine-loops at any point.

Upon completion of the study, data will be pseudonymized, and only pseudonymized data will be used for analysis and potential data sharing. Access to data will require approval of a research proposal and will be subject to relevant ethical and data protection regulations. Requests for data access can be made to the principal investigator.

Data transfer takes place within the EU/EEA and complies with the General Data Protection Regulation. Local legislation and national ethical requirements will be respected at each participating site. Study data will be stored for 5 years after publication in accordance with institutional policy.

Compensation and benefits to participants

Participants will not receive any financial compensation, reimbursement of expenses, or other benefits for participation in the study, as the study involves minimal risk and no additional visits beyond standard ED care.

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