A Randomized Trial of Blinded vs Unblinded Sepsis Biomarker Monitoring in Burn Patients

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ABSTRACT:

Early recognition of sepsis in critically ill burn patients is challenging due to profound sterile inflammation from burn injury and repeated surgical interventions, which limits the specificity of conventional biomarkers such as C-reactive protein and procalcitonin. These limitations contribute to delayed diagnosis, prolonged antibiotic exposure, and worse clinical outcomes. Pancreatic stone protein (PSP) has emerged as a promising sepsis biomarker that appears less affected by noninfectious inflammation and may rise earlier than traditional markers in burn-associated sepsis. This investigator-initiated, randomized interventional study will evaluate whether unblinded, serial PSP monitoring improves sepsis management compared with standard care with blinded biomarker monitoring. Adult patients admitted to a burn intensive care unit with thermal injury will be randomized to either standard of care with blinded PSP measurements or an intervention arm in which PSP results are unblinded and incorporated into structured clinical decision-making to guide antibiotic initiation and escalation. In both groups, sepsis evaluation and treatment will otherwise follow established institutional protocols and guideline-directed care. The primary outcome is time from onset of sepsis to initiation of appropriate antibiotic therapy. Secondary outcomes include duration of broad-spectrum antibiotic use, incidence of organ dysfunction, antibiotic-free days, intensive care unit length of stay, and in-hospital mortality. This study will provide critical evidence on the clinical utility and safety of PSP-guided monitoring in burn patients and inform integration of biomarker-guided strategies into sepsis care for this high-risk population.

AIMS:

To evaluate whether unblinded, serial monitoring of pancreatic stone protein (PSP) integrated into routine burn ICU care improves the timeliness and safety of sepsis management compared with standard care with blinded PSP monitoring.

OBJECTIVES:

Primary Objective

To compare time from suspected or confirmed sepsis onset to initiation of appropriate antibiotic therapy between patients managed with unblinded PSP-guided monitoring and those receiving standard care.

Secondary Objectives

1. To compare antibiotic utilization between groups, including antibiotic-free days and duration of broad-spectrum antibiotic therapy.
2. To assess differences in clinical outcomes, including organ dysfunction severity, intensive care unit length of stay, and in-hospital mortality.
3. To evaluate the diagnostic performance of serial PSP measurements for early sepsis detection relative to C-reactive protein and procalcitonin.

Exploratory Objectives

1. To assess the feasibility and safety of incorporating unblinded PSP monitoring into routine clinical workflows, including rates of potentially unnecessary antibiotic initiation or delayed escalation.
2. To explore PSP performance in predefined high-risk subgroups, including patients with inhalation injury and larger total body surface area burns.

HYPOTHESIS:

Adding PSP to clinical assessment will enhance clinicians' ability to rapidly recognize and treat sepsis in patients with burn injuries.

BACKGROUND/SIGNIFICANCE:

Sepsis remains a major cause of morbidity and mortality in critically ill burn patients, whose baseline hyperinflammatory state and frequent invasive procedures make early recognition of infection particularly difficult. Traditional biomarkers such as C-reactive protein (CRP) and procalcitonin (PCT) rise in response to sterile inflammation, surgical debridement, and trauma, limiting their specificity for sepsis in the burn intensive care unit (ICU) population. As a result, delays and inaccuracies in sepsis diagnosis continue to contribute to organ dysfunction, prolonged ICU stays, and high mortality despite implementation of contemporary sepsis bundles [1,3].

Pancreatic stone protein (PSP) has emerged as a promising biomarker for early sepsis detection in critically ill and burn patients [1-3]. PSP, a secretory protein produced predominantly by pancreatic acinar cells, is up-regulated during systemic infection and organ dysfunction and appears less sensitive to noninfectious inflammatory stimuli than CRP and PCT. In severely burned ICU cohorts, PSP concentrations remain relatively stable after burn injury and repeated surgical procedures in the absence of sepsis, whereas CRP and PCT increase significantly, suggesting better specificity for infectious complications. When sepsis develops, PSP can rise several-fold up to 48–72 hours before clinical diagnosis and has outperformed CRP and PCT in both absolute levels and kinetics for early sepsis recognition in burn patients, including those with inhalation injury and acute respiratory distress syndrome [1].

Beyond burn populations, observational ICU studies and reviews have demonstrated that PSP has diagnostic and prognostic accuracy for sepsis, often comparable to or better than CRP and sometimes similar to PCT, particularly when used in serial measurements [2,3,5]. Rapid point-of-care assays for PSP have obtained regulatory clearance as aids for early sepsis detection, supporting the analytical reliability and feasibility of PSP testing in acute care settings [3,4]. PSP measurement itself uses standard blood sampling and has not been associated with specific safety concerns beyond routine phlebotomy [2-4].

Despite these advantages, PSP is best considered an adjunct rather than a replacement for comprehensive clinical assessment and standard sepsis care. Over-reliance on any single biomarker can lead to both overtreatment and undertreatment; therefore, integrating serial PSP trends with thorough bedside evaluation, organ dysfunction scores, microbiology, and guideline-directed therapies is essential [3-5]. An investigator-initiated trial of PSP-guided monitoring in the burn ICU will address critical evidence gaps and clarify whether this strategy can improve the timeliness and accuracy of sepsis recognition, reduce mortality, and preserve adherence to established standards of care.

METHODS:

This is a randomized, controlled trial evaluating the clinical use of PSP results to guide/augment clinical decision-making regarding the onset and management of sepsis in the Burn ICU. Subjects will be adults admitted to the study site with a diagnosis of burn injury who are deemed critically ill and require ICU admission. Patients will be recruited for participation after admission to the Burn Center.

Inclusion Criteria:

1. Adults aged 18 – 89 years
2. Diagnosed with Burn injury of any mechanism
3. Admitted to the Burn Surgical Team at UMC Hospital with a critical condition/ICU status. Critically ill burns overflowed to TSICU may still be enrolled.
4. Expected ICU stay $\geq$ 48 hours
5. Subject will be approached during the first 24 hours after burn injury with an invitation to participate
6. Admission date beginning April 1, 2026 and extending for 2 years until March 31, 2028.

Exclusion Criteria:

1. Prisoners
2. Incomplete chart data
3. Acute or chronic pancreatitis
4. Abdominal pathologies
5. Advanced renal failure (acute or chronic)
6. Pre-existing multiple organ failure
7. Inability to approach/consent within 24 hours after the time of injury
8. Existing sepsis requiring antibiotics within 24 hours of admission
9. Limited life span, expected death within 3 days of admission due to the severity of injury
10. Lower acuity burns admitted to the burn stepdown.

Site of Study: UMC Hospital and TTUHSC.

Screening and Recruitment:

The study team will screen the EC, Burn Center, and TSICU clinical locations for patients who meet the inclusion criteria using the EHR. As the study team identifies patients, they will review the chart to ensure no exclusion criteria exist. The study team will contact the Investigator team to ensure the patient meets study criteria. After the study team obtains verbal permission to approach from the PI, the study coordinator/s will approach the patient or the legally authorized representative (LAR) with an invitation to participate in the research study. The patient/LAR will be approached in a private location, and family/companions will be encouraged to participate according to the patient's wishes. Because of the urgent nature of the study, consent will be obtained during initial contact. If the patient or LAR wishes more time to consider the enrollment decision, that will be provided, as long as time allows. If the patient or LAR are not able to decide about enrollment before the 24 hours since time of injury inclusion criteria runs out, they will not be enrolled. Time of consent will be recorded in the enrollment log.

The study coordinator/s will emphasize that enrollment will not affect the patient's relationship with their doctor or medical team and that they will be provided excellent care regardless of participation.

Study Design

This study is a prospective, randomized, controlled clinical utility trial conducted in a single Burn Intensive Care Unit (BICU). Eligible burn patients will be randomized in a 1:1 ratio to either a blinded PSP monitoring arm (control) or an unblinded PSP-guided management arm (intervention). The intervention under study is the availability and clinical use of PSP results to guide/augment clinical decision making, not the blood draw itself.

Randomization: Patients will be randomly assigned by a computer to one of the two study groups at the time of enrollment. To keep the groups balanced and prevent predictability, assignments are generated in advance using randomly varying block sizes. Randomization is performed separately within burn severity categories (< 30% TBSA or > 30% TBSA) and by presence or absence of inhalation injury, ensuring that key clinical risk factors are evenly distributed between the two groups. Graphpad is an already approved, paid, and installed desktop application that is not cloud-based. No data elements will be entered into Graphpad. The study team will enter the the burn severity and inhalation groups, and the randomization groups. Graphpad will generate assignments for each group. Example: <30% TBSA + Inhalation Injury. Block randomization schedule (B is Blinded, U is Unblinded): BB UU BBB U B UU B UU.

Study Arms

Control Arm: Blinded PSP Monitoring (Standard of Care)

Participants randomized to the control arm will have PSP levels measured according to the study schedule; however, PSP results will be blinded to the treating clinical team and will not be used to guide clinical decision-making. PSP values will be recorded in a secure research database accessible only to the study team. Clinical management, including decisions regarding antibiotics, cultures, and sepsis evaluation, will follow standard Burn practice based on clinical assessment and existing laboratory and physiologic data.

Intervention Arm: Unblinded PSP-Guided Management

Participants randomized to the intervention arm will have PSP results made available to the treating clinical team in real time. Clinical management will be guided/augmented by the predefined PSP-based algorithm integrated with clinical judgment:

Interpretation and Clinical Application:

- PSP cut-off values: The following table presents the proposed clinical cut-off values for PSP:

	Risk of sepsis	Suggested action
PSP < 100 ng/ml	Low risk of sepsis	Low risk of sepsis. No action needed
PSP ≥ 100 - 200 ng/ml	Moderate risk of sepsis	Moderate to high risk of sepsis

PSP ≥ 200 - 300 ng/ml	High risk of sepsis	Decision based on clinical evaluation, likely to start administering antibiotics and apply evidence-based sepsis management
PSP ≥ 300 ng/ml	Very High risk of sepsis	Rapidly administer antibiotics and apply evidenced-based sepsis management

- Results should be interpreted with caution in patients with acute or chronic pancreatitis, abdominal pathologies, advanced renal failure (acute or chronic), or pre-existing multiple organ failure. These patients should not be enrolled based on exclusion criteria.
- Rising PSP trends over consecutive measurements may indicate the early onset of sepsis, even if levels are within a lower range.
    - **Antibiotic Indications:** Recommend starting antibiotics if any of the following occur, and/or based on clinical judgement:
        - **PSP level ≥ 200 ng/mL**
- Clinicians may override the algorithm at any time if deemed necessary for patient safety; the rationale for deviations will be documented for fidelity analysis.

PSP Measurement Schedule

PSP measurements will be obtained:

- Within 24 hours of Burn ICU admission (baseline)
- Week days during the ICU stay up to 45 days
- If a patient in the unblinded arm is over 200 ng/mL for PSP OR their values have doubled once in the previous 3 days, one weekend test will be performed.
- If a patient in the blinded arm is actively undergoing sepsis management, one weekend test will be performed.
- Additionally at times of acute clinical deterioration or new concern for infection, at the discretion of the clinical team

The frequency of scheduled PSP measurements will remain standard and should match for all study participants. Additional PSP checks deemed necessary by the clinical team may differ between participants.

Study visits/Roles of subjects:
Visit 1: Informed consent, randomization, specimen collection by a study team member (or a member of the clinical team), A schedule is made for the remaining visits.

Consent will be obtained from the patient or LAR after thoroughly reviewing the consent form and answering all questions as they arise.

The first blood sample will be collected within 24 hours of Burn ICU admission, not burn injury.

Daily check of the PSP measurement: the study team, or a member of the clinical team, will collect the research-specific blood specimen in a 3 mL EDTA tube. The 50 microliter sample will be taken from this 3 mL collection. Chart data will also be collected by the study team, see data collection sheet.

Materials, Instruments or Measurements:
A member of the study team will access each participant's electronic health record to validate eligibility and collect data.

Two abioSCOPE devices have been provided by Abionic, along with testing kits. One device will be kept in the Burn unit for the unblinded arm. The other unit will be kept in the CRI lab for the blinded arm. The abioSCOPE device is about the size of a computer tower. The kits are individually about the size of a notecard, ½ inch thick.

No blood will be shipped or stored. Blood samples will be discarded after testing.

IVD MEDICAL DEVICE DESCRIPTION

Background of Device

The abioSCOPE and the IVD CAPSULE PSP are manufactured by Abionic SA (Epalinges, Switzerland). They are FDA-cleared and CE-marked according to the *In vitro* Diagnostic Regulation (IVDR) 2017/746. The IVD CAPSULE PSP is a single-use *in vitro* diagnostic device designed to measure Pancreatic Stone Protein (PSP) in human whole blood. PSP is a highly sensitive and early biomarker that enables the identification of patients at high risk of developing sepsis. The test requires only 50 µL of whole blood collected in EDTA and provides results within 10 minutes. It is designed for use with the abioSCOPE®, a compact tabletop diagnostic device that measures analytes in biological samples with high precision.

The IVD CAPSULE PSP (REF. P02.00026) kit includes a disposable PSP capsule, a sample handling device (abioPIPETTE) and a reagent (abioMIX reagent). The abioSCOPE instrument (REF. P01.00007) is an easy-to-operate, automated immunoassay analyzer with a small footprint. It can run on demand with short turnaround time. It comprises a high-resolution touchscreen, a fully automated fluorescent microscope, and a mounting plate which accepts a single-use, disposable, assay-specific capsule. The abioSCOPE instrument uses calibration information encoded in the capsule along with the measured fluorescent signal to report the amount of PSP in the sample, expressed in ng/mL.

Briefly, using the abioPIPETTE, a single drop of blood is mixed with the abioMIX reagent and loaded onto a port of the PSP capsule. The sample is drawn through the capsule by capillary action and passes through a built-in separator that excludes particles from the measurement area. The formed PSP-antibody complex is bound by anti-human PSP capture antibodies immobilized within the capsule's reading area. The concentration of PSP in the sample is proportional to the fluorescence generated in the reading area. None of the components of the devices has direct contact with patient tissues or fluids. No medical or surgical procedures are involved in the use of the device. Use of the IVD CAPSULE PSP on the abioSCOPE device requires personnel to have competence in device operation and sample handling. The Instructions for Use (IFU) for the IVD CAPSULE PSP and the User manual for the abioSCOPE will be made available to all study personnel involved in the study. Only trained and authorized study staff will be permitted to operate the device. Training will include both

theoretical instruction and hands-on demonstrations to ensure proper use and minimize potential risks. Training documentation will be maintained by the study team throughout the study.

Intended Use of Device

IVD CAPSULE PSP

The IVD CAPSULE PSP is a single-use, rapid in vitro diagnostic test for the quantitative measurement of pancreatic stone protein (PSP) in human capillary whole blood, as well as in K2-EDTA, K3-EDTA, and lithium heparin anticoagulated venous and arterial whole blood. The IVD CAPSULE PSP is to be used with the abioSCOPE 2.0 in vitro diagnostic test system. The IVD CAPSULE PSP is used in conjunction with other clinical assessments and laboratory findings to aid in the early recognition of sepsis in adults.

abioSCOPE

The abioSCOPE is a tabletop diagnostic device that measures analytes in biological samples using test-specific capsules (IVD CAPSULE) intended for use with this instrument.

Device traceability

Traceability of the IVD CAPSULE PSP on the abioSCOPE device will be maintained throughout the clinical investigation and after its completion. Each device will be identified and tracked by its unique lot number, or serial number, as applicable. The specimen & device accountability log will track not only subject specimens but also the lot numbers of the kits and the device's serial number.

Procedures for Device Accountability

All single-use IVD CAPSULE PSP kits will be recorded upon receipt, including lot numbers and quantities. The reusable abioSCOPE devices will also be logged with their unique serial numbers, and each device’s use and maintenance will be tracked throughout the study. Device accountability logs will be verified during monitoring visits to ensure complete traceability.

Procedures for Safe Handling, Maintenance, and Return

The IVD CAPSULE PSP kits will be disposed of after use in accordance with biosafety guidelines and local regulations, with documentation of lot numbers and disposal dates. abioSCOPE devices will be maintained and cleaned according to the manufacturer’s instructions. At the end of the study, abioSCOPE devices will be returned to the sponsor or designated facility for proper storage, maintenance, or redeployment. All handling, maintenance, and return activities will be fully documented to ensure regulatory compliance and traceability.

Risk/Benefit Assessment

Known Potential Risks

The IVD CAPSULE PSP on the abioSCOPE device is an *in vitro* diagnostic assay. The only study assessment that has a potential participant risk related to the PSP measurement is blood collection. The risk to the participant is minimal; fainting, lightheadedness, bruising, pain, and infection are typically associated with a blood draw. When feasible, the PSP blood draw will be performed

concurrently with clinical care blood draws to minimize patient discomfort. Safety issues related to treatment are discussed in the chapter “Safety”.

Potential Product Benefits

The potential benefits include early sepsis detection with the device under investigation, leading to earlier treatment and better patient outcomes, i.e., reduced sepsis cases.

Assessment of Potential Risks and Benefits

Participation in the study involves only a minor risk of blood sampling and may lead to better patient outcomes.

LABORATORY PROCEDURES

PSP measurements

For the blood sampling and the PSP measurement, the IVD CAPSULE PSP will be used. The measurement can be performed on whole venous/arterial blood collected in a tube containing K_2/K_3 EDTA as anticoagulant. 50 µL of blood (~ 1 drop of blood) will be collected using the special abioPIPETTE device included in the test kit. The 50 µL of blood will be transferred into the vial containing the reaction solution. After thoroughly mixing the vial by tapping it against a hard surface at least 10 times, 50 µL of the mixture will be transferred into the special capsule, and the PSP measurement will be performed on the abioSCOPE 2.0 device according to the manufacturer's instructions.

Outcomes

Primary Outcome

The primary outcome is time from sepsis onset to initiation (order) of empiric antibiotics

Secondary Outcomes

Secondary outcomes include:

- Decrease of sepsis prevalence
- Time from sepsis onset to discontinuation of vasopressors for ≥24 consecutive hours
- Antibiotic exposure, measured as antibiotic days of therapy per 100 ICU days
- Antibiotic exposure, measured as antibiotic days of therapy per 100 hospital days
- Antibiotic-free days through day 28
- ICU length of stay
- In-hospital mortality
- Frequency and timing of diagnostic evaluations for infection (blood cultures, imaging)
- Rate of recurrent sepsis episodes during the index hospitalization
- Safety outcomes, including acute kidney injury, *Clostridium difficile* infection, and antibiotic-related adverse events

- Protocol adherence and frequency of algorithm overrides in the PSP-guided arm
- Pharmacoeconomic impact of PSP monitoring

The primary endpoint is the time (in hours) from sepsis onset (t0) to resolution of sepsis-associated organ dysfunction.

- Sepsis onset (t0) is defined as the first time the patient meets operational Sepsis-3 criteria, specifically suspected infection (initiation or escalation of antibiotics with culture acquisition) in conjunction with an increase in SOFA of ≥2 points above baseline within a 24-hour window.
- Baseline SOFA ($bSOFA_0$) is defined as the SOFA score calculated using the worst physiologic values within 24 ± 6 hours after Burn ICU admission (or completion of initial resuscitation). Daily SOFA (SOFA_d) scores are calculated using the worst values in each subsequent 24-hour period. ΔSOFA is calculated as SOFA_d − $bSOFA_0$.
- Resolution is defined as the start of the first sustained 48-hour period during which the patient demonstrates a decrease in SOFA score such that the change from baseline (ΔSOFA) is <2 points.

Statistical Analysis

Analyses will be performed by TTUHSC. All analyses will follow the intention-to-treat principle, with participants analyzed according to their randomized study arm (control arm: standard care, PSP measured but blinded, intervention group: unblinded PSP guided monitoring) regardless of protocol adherence. Baseline demographic and clinical characteristics will be summarized using descriptive statistics to assess the balance between study arms. Continuous variables will be reported as a mean ± standard deviation (SD) or median with interquartile range (IQR), based on normality assumption. Categorical variables will be summarized as counts and/or percentages. All hypothesis tests will be 2-sided with an alpha level of 0.05 for the primary endpoint.

The primary endpoint, time to resolution of sepsis-associated organ dysfunction, will be analyzed as a time-to-event outcome. Time zero (t0) is defined as sepsis onset, as specified in the Outcomes section. Participants will be followed until achievement of sustained organ dysfunction resolution and censored at ICU discharge, death, or day 28, whichever occurs first.

The primary comparison between study arms will be performed using a Cox proportional hazards regression model, with study arm as the primary independent variable. Results will be reported as hazard ratios with 95% confidence intervals. Models will adjust for prespecified baseline covariates known to influence sepsis outcomes in burn patients, including baseline SOFA score, total body surface area category, and presence of inhalation injury. The proportional hazards assumption will be assessed using standard diagnostic such as, Schoenfeld residuals and log–log plots. If the proportional hazards assumption is materially violated, alternative approaches such as stratification, time-dependent coefficients, or time-interval splitting will be considered as sensitivity analyses.

Secondary outcomes will be analyzed using statistical methods appropriate to the type of outcome and aligned with the study objectives related to antibiotic exposure, clinical outcomes, diagnostic

evaluations, feasibility, and safety outcomes. Time-to-event secondary outcomes such as time from sepsis onset to initiation and time from sepsis onset to discontinuation of vasopressors, will be analyzed using Cox regression. For these outcomes, cumulative incidence curves or Kaplan–Meier curves will be used for visualization, and effect estimates will be reported as hazard ratios with 95% confidence intervals.

Count outcomes, including ICU length of stay (LOS), hospital length of stay will be analyzed using count-data regression models, with results reported as incidence rate ratios (IRR) and 95% confidence intervals (CI). Binary outcomes, including in-hospital mortality, recurrent sepsis episode, acute kidney injury (AKI), *clostridium difficile* infection, occurrence of antibiotic-related adverse event will be analyzed using logistic regression, with results reported as odds ratios (OR) and 95% CIs. Continuous outcomes that are approximately symmetric will be analyzed with linear regression, while non-normal continuous outcomes may be analyzed using generalized linear models with appropriate distribution and link functions.

Given the pilot nature of this study, analyses are intended to estimate effect sizes, variability, and feasibility metrics rather than to definitively test efficacy hypotheses. This information will inform the design of future larger multicenter studies.

Sample Size Estimation

This is a pilot randomized clinical utility trial designed to estimate the effect of PSP-guided management on time to resolution of sepsis-associated organ dysfunction and to assess feasibility and protocol adherence. A total sample size of 120 patients (60 per arm) is expected to yield approximately 50 resolution events, providing sufficient precision to estimate the hazard ratio and inform the sample size for a subsequent full-power efficacy trial [1-3].

Ethical Considerations

Both study arms receive at least standard-of-care sepsis management. PSP-guided management is not an established standard practice in burn patients; therefore, blinding PSP results in the control arm does not deprive participants of proven therapy. **All patients remain under continuous clinical assessment, and clinicians may initiate sepsis treatment at any time based on clinical judgment, regardless of study arm.**

Risks:

Breach of confidentiality is a risk for this study. All data will be stored in the principal investigator's encrypted folder in the Box storage account or in the REDCap database. This account is set up by the study site and approved for protected health information by the study site.

Benefits: (To participants or the public at large)

There are no guaranteed direct benefits to the subject. All subjects will receive standard-of-care treatment by their clinical teams. However, the PSP arm may have information that supports rapid sepsis diagnosis, leading to earlier treatment. This could potentially result in improved management, but no guarantees are being made. The general contribution of knowledge in treating patients with burn injuries and those with sepsis could potentially be significant. The dissemination

of any findings may contribute to significant changes in the management of patients with burns for multidisciplinary clinicians (physicians, nurses, therapists, social workers, case management, etc.).

Confidentiality:

Enrollment data and regulatory study documents will be kept by the CRI on the secure research server, Disk-1, accessible only to the CRI team. All source documentation will be kept inside the EHR. All shared data will be stored in the study team's encrypted folder in the Box storage account or in the REDCap database. This account is set up by the study site and approved for protected health information by the study site. Only approved study personnel will be given access to the study folder with data.

The Protected Health Information and Patient Identifiers collected for the screening and enrollment log will not be shared with any outside entity. Only the internal TTUHSC study team will have access to the subject screening and enrollment log. This data will be kept inside the Protected research server owned by the CRI. Any data shared with the sponsor will be de-identified using only subject ID.

AI Use for Research:
The research team will not use AI/generative AI for this research project, except for the AI tools inherently incorporated into the Epic Electronic Health Record system, which explicitly protect TTUHSC data and our patients' data.

Monitoring:
Internal monitoring will be performed by the CRI monitor in a risk-based manner.

Reimbursement:
The subject will receive no reimbursement for participation in this research.

Funding:
Funding for this study is provided by Abionic. Other departmental funding will be provided by the Department of Surgery as needed.

Consent Form:
See attached ICF.

Acknowledgements:
Gratitude to the CRI for their help in preparing this protocol and supporting enrollment and patient visits for this study.

References

1. Klein H, Steiger P, Giovanoli P, Reding T, Graf R, Plock JA. Pancreatic stone protein predicts sepsis in severely burned patients irrespective of trauma severity. Ann Surg. 2021;274(6):e1179–e1186.

2. Llewelyn MJ, Berger A, Grouzmann E, et al. Pancreatic stone protein as a biomarker for sepsis at the emergency department: a prospective observational study. Crit Care. 2022;26(1):126.
3. Eggimann P, Que YA, Revelly JP, Pagani JL. Pancreatic stone protein: a marker of sepsis at the bedside? J Clin Med. 2022;11(4):1085.
4. Ventura V. Pancreatic stone protein measurement to screen and diagnose sepsis in the context of the Surviving Sepsis Campaign recommendations. Med Res Arch. 2023;11(12):4893.
5. Monneret G, et al. Serial monitoring of pancreatic stone protein for the detection of sepsis in intensive care unit patients with complicated abdominal surgery. J Crit Care. 2024;79:154–162.
6. Rech MA, Mosier MJ, McConkey K, Zelisko S, Netzer G, Kovacs EJ, Afshar M. Outcomes in Burn-Injured Patients Who Develop Sepsis. J Burn Care Res. 2019 Apr 26;40(3):269-273. doi: 10.1093/jbcr/irz017. PMID: 30805641; PMCID: PMC7185196.
7. Dvorak JE, Ladhani HA, Claridge JA. Review of Sepsis in Burn Patients in 2020. Surg Infect (Larchmt). 2021 Feb;22(1):37-43. doi: 10.1089/sur.2020.367. Epub 2020 Oct 23. Erratum in: Surg Infect (Larchmt). 2021 Nov;22(9):989. doi: 10.1089/sur.2020.367.correx. PMID: 33095105.
8. Tedesco DJ, Hutter MF, Khalaf F, Ricciuti Z, Jeschke MG. Sepsis in burn care: incidence and outcomes. Mil Med Res. 2025 Sep 1;12(1):55. doi: 10.1186/s40779-025-00643-x. PMID: 40890875; PMCID: PMC12403279.