Comparison of Sacral Interface Pressure in Healthy Volunteers on Two Dynamic Pressure-Prevention Support Surfaces

Study Protocol & Statistical Analysis Plan

NCT06661954

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Comparison of Sacral Interface Pressure in Healthy Volunteers on Two Dynamic Pressure-Prevention Support Surfaces

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Sponsor: University of Alabama at Birmingham

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STATEMENT OF COMPLIANCE

The trial will be carried out in accordance with International Conference on Harmonisation Good Clinical Practice (ICH GCP) and the following:

- United States (US) Code of Federal Regulations (CFR) applicable to clinical studies (45 CFR Part 46, 21 CFR Part 50, 21 CFR Part 56, 21 CFR Part 312, and/or 21 CFR Part 812)

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the Institutional Review Board (IRB) for review and approval. Approval of both the protocol and the consent form must be obtained before any participant is enrolled. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. In addition, all changes to the consent form will be IRB-approved; a determination will be made regarding whether a new consent needs to be obtained from participants who provided consent, using a previously approved consent form.

1 PROTOCOL SUMMARY

1.1 SYNOPSIS

Title:	Comparison of Sacral Interface Pressure in Healthy Volunteers on Two Dynamic Pressure-Prevention Support Surfaces
Study Description:	*Participants will have their sacral pressure measured for 15 minutes on each of four test conditions. The test conditions are all combinations of two bed systems and two head of bed positions. Assessment order will be randomized. There are no hypotheses.*
Objectives:	*To investigate the peak sacral interface pressure of two hospital bed systems in the supine and 30 degrees head of bed position*
Endpoints:	*Peak Sacral Pressure (mm Hg)*
Study Population:	*A total of 18 non-disabled adults age 18 years or older living in the United States.*
Phase:	NA
Description of Sites/Facilities Enrolling Participants:	*One Academic Medical Center in the United States*
Description of Study Intervention:	*Participants will have their sacral pressure measured for 15 minutes on each of four test conditions. The test conditions are all combinations of two bed systems and two head of bed positions. Assessment order will be randomized.*
Study Duration:	*1 year*
Participant Duration:	*One visit of 60-90 minutes*

1.2 SCHEDULE OF ACTIVITIES (SOA)

Schedule of Activities (SoA)

Procedures	Visit to Simulation Laboratory (1 visit for 60-90 minutes)
Informed consent	X
Demographics (age, sex, height, weight)	X
Randomization of testing order	X
Measure pressure of the four test conditions	X

2 INTRODUCTION

2.1 STUDY RATIONALE AND BACKGROUND

Hospital-acquired pressure injuries remain a major healthcare concern and pose a significant medical and financial burden to patients and hospital systems. Hospitals are required to report pressure injuries as part of quality improvement metrics however this can also lead to penalties in terms of reimbursement. In recent years, the Centers for Medicare and Medicaid Services (CMS) have established that they will not reimburse care for hospital-acquired pressure injuries which includes stage 2, 3, 4 and deep tissue or unstageable pressure injuries that are not documented within the first 24 hours of hospitalization. Patients with spinal cord injuries are at increased risk for pressure injuries during the acute hospitalization phase due to factors such as impaired sensation to provide feedback to change positions, impaired mobility, autonomic dysfunction, tissue hypo-perfusion, and bowel or bladder incontinence.

2.2 RISK/BENEFIT ASSESSMENT

2.2.1 KNOWN POTENTIAL RISKS

The only known potential risk is falling or musculoskeletal injury when moving between bed systems.

2.2.2 KNOWN POTENTIAL BENEFITS

There are no known direct benefits to individuals who participate.

The study will increase knowledge of pressure relieving capabilities of the current hospital bed systems and allow researchers to consider implications of ongoing use of these bed systems including risk of further pressure injuries, impacts on hospital quality metrics, and costs to hospital system. The information obtained from this study will allow the researchers to improve their knowledge and care for the patients in inpatient rehabilitation.

3 STUDY DESIGN

3.1 OVERALL DESIGN

The overall design was a crossover pilot repeated measures with randomization. There were no hypothesis and all study activities occurred at a single location. The 'interventions' assessed were mattress type (low air loss, standard hospital mattress) and head of bed position (0^o, 30^o). All combinations of the interventions were assessed on each participant (4 unique combinations). There was one study arm and study duration was 60-90 minutes during a single visit to the testing location. Sequence of assessment of the combinations was randomized to reduce potential sequence effects. No interim analysis was planned. There were no stratifications and no sub-studies. No measures to minimize bias were implemented.

3.2 END OF STUDY DEFINITION

A participant is considered to have completed the study if he or she has had their sacral pressure recorded for 15 minutes on each of the four test conditions.

The end of the study is defined as completion of the data collection protocol by the last participant.

4 STUDY POPULATION

4.1 INCLUSION CRITERIA

In order to be eligible to participate in this study, an individual must meet all of the following criteria

- Age >=18
- non-disabled
- can walk & stand independently
- can visit UAB SIM Lab once for 75 minutes.

4.2 EXCLUSION CRITERIA

An individual who meets any of the following criteria will be excluded from participation in this study:

- Self-reported sacral skin breakdown or other sacral skin condition which could be made worse by participation in this study.

4.3 STRATEGIES FOR RECRUITMENT AND RETENTION

Individuals will be recruited from the study team's personal and professional networks. Information sheets may be distributed via email. Information may be shared during departmental lectures and

meetings. Individuals can participate if they are employees, medical students, residents, and faculty of the host institution. Compensation and/or incentives will not be offered to individuals who participate

5 STUDY INTERVENTION

5.1 STUDY INTERVENTION(S) ADMINISTRATION

5.1.1 STUDY INTERVENTION DESCRIPTION

Each participant will undergo sacral interface pressure mapping on two different beds (A and B) in the supine (head-of-bed at 0 degrees) and elevated (head-of-bed at 30 degrees) positions. Bed sequence combinations will be randomized. In each bed and position, a sacral pressure mapping interface system will be placed under the participant's sacrum for a 15 minute period. Peak interface pressure (mm Hg) will be captured at every minute. Interface pressure may be recorded continuously during each bed-position combination if the pressure mapping system used has the capacity.

5.2 MEASURES TO MINIMIZE BIAS: RANDOMIZATION AND BLINDING

Testing order of the four tested conditions will be randomized. No blinding will be implemented.

5.3 STUDY INTERVENTION COMPLIANCE

The study team will document completion of the study protocol as in compliance with the approved protocol. Any deviations from the protocol will be documented.

6 STUDY INTERVENTION DISCONTINUATION AND PARTICIPANT DISCONTINUATION/WITHDRAWAL

6.1 DISCONTINUATION OF STUDY INTERVENTION

There are no predefined criteria for discontinuation of the study intervention.

6.2 PARTICIPANT DISCONTINUATION/WITHDRAWAL FROM THE STUDY

Participants are free to withdraw from participation in the study at any time upon request.

An investigator may discontinue or withdraw a participant from the study for the following reasons:

- Significant study intervention non-compliance
- If any adverse event (AE), other medical condition or situation occurs such that continued participation in the study would not be in the best interest of the participant

- If the participant meets an exclusion criterion (either newly developed or not previously recognized) that precludes further study participation

The reason for participant discontinuation or withdrawal from the study will be recorded. Subjects who sign the informed consent form and are randomized but do not receive the study intervention may be replaced. Subjects who sign the informed consent form, and are randomized and receive the study intervention, and subsequently withdraw, or are withdrawn or discontinued from the study, may be replaced.

7 STUDY ASSESSMENTS AND PROCEDURES

7.1 EFFICACY ASSESSMENTS

The primary outcome is peak sacral pressure on each of the four tested conditions.

Each participant will undergo sacral interface pressure mapping on two different beds (A and B) in the supine (head-of-bed at 0 degrees) and elevated (head-of-bed at 30 degrees) positions. Bed sequence combinations will be randomized. In each bed and position, a sacral pressure mapping interface system will be placed under the participant's sacrum for a 15 minute period. Peak interface pressure (mm Hg) will be captured at every minute. Interface pressure may be recorded continuously during each bed-position combination if the pressure mapping system used has the capacity.

7.2 SAFETY AND OTHER ASSESSMENTS

Safety assessments were not planned. This protocol was determined to be of minimal risk to participants and met the criteria for expedited review.

7.3 ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS

7.3.1 DEFINITION OF ADVERSE EVENTS (AE)

Adverse event means any untoward medical occurrence associated with the use of an intervention in humans, whether or not considered intervention-related (21 CFR 312.32 (a)).

7.3.2 DEFINITION OF SERIOUS ADVERSE EVENTS (SAE)

An adverse event (AE) or suspected adverse reaction is considered "serious" if, in the view of either the investigator or sponsor, it results in any of the following outcomes: death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the participant and may require medical or surgical intervention to prevent one of

the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse

7.3.3 CLASSIFICATION OF AN ADVERSE EVENT

7.3.3.1 SEVERITY OF EVENT

For adverse events (AEs) not included in the protocol defined grading system, the following guidelines will be used to describe severity.

- **Mild** – Events require minimal or no treatment and do not interfere with the participant's daily activities.
- **Moderate** – Events result in a low level of inconvenience or concern with the therapeutic measures. Moderate events may cause some interference with functioning.
- **Severe** – Events interrupt a participant's usual daily activity and may require systemic drug therapy or other treatment. Severe events are usually potentially life-threatening or incapacitating. Of note, the term "severe" does not necessarily equate to "serious".]

7.3.3.2 RELATIONSHIP TO STUDY INTERVENTION

All adverse events (AEs) must have their relationship to study intervention assessed by the clinician who examines and evaluates the participant based on temporal relationship and his/her clinical judgment. The degree of certainty about causality will be graded using the categories below. In a clinical trial, the study product must always be suspect.

- **Related** – The AE is known to occur with the study intervention, there is a reasonable possibility that the study intervention caused the AE, or there is a temporal relationship between the study intervention and event. Reasonable possibility means that there is evidence to suggest a causal relationship between the study intervention and the AE.

- **Not Related** – There is not a reasonable possibility that the administration of the study intervention caused the event, there is no temporal relationship between the study intervention and event onset, or an alternate etiology has been established.

7.3.3.3 EXPECTEDNESS

The PI will be responsible for determining whether an adverse event (AE) is expected or unexpected. An AE will be considered unexpected if the nature, severity, or frequency of the event is not consistent with the risk information previously described for the study intervention.

7.3.4 TIME PERIOD AND FREQUENCY FOR EVENT ASSESSMENT AND FOLLOW-UP

The occurrence of an adverse event (AE) or serious adverse event (SAE) may come to the attention of study personnel during the study visit.

All AEs including local and systemic reactions not meeting the criteria for SAEs will be recorded. Information to be collected includes event description, time of onset, assessment of severity, relationship to study product (assessed only by those with the training and authority to make a diagnosis), and time of resolution/stabilization of the event. All AEs occurring while on study must be documented appropriately regardless of relationship. All AEs will be followed to adequate resolution.

Any medical condition that is present at the time that the participant is screened will be considered as baseline and not reported as an AE. However, if the study participant's condition deteriorates at any time during the study, it will be recorded as an AE.

Changes in the severity of an AE will be documented to allow an assessment of the duration of the event at each level of severity to be performed. AEs characterized as intermittent require documentation of onset and duration of each episode.

<Insert role or name> will record all reportable events with start dates occurring any time after informed consent during the study visit. Events will be followed for outcome information until resolution or stabilization.

7.3.5 ADVERSE AND SERIOUS ADVERSE EVENT REPORTING

The study investigator shall report any adverse event to the reviewing Institutional Review Board (IRB) as a part of the next continuing review.

The study investigator shall report any serious adverse event to the reviewing Institutional Review Board (IRB) as soon as possible, but in no event later than 10 working days after the investigator first learns of the effect.

7.4 UNANTICIPATED PROBLEMS

7.4.1 DEFINITION OF UNANTICIPATED PROBLEMS (UP)

The Office for Human Research Protections (OHRP) considers unanticipated problems involving risks to participants or others to include, in general, any incident, experience, or outcome that meets **all** of the following criteria:

- Unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the Institutional Review Board (IRB)-approved research protocol and informed consent document; and (b) the characteristics of the participant population being studied;
- Related or possibly related to participation in the research ("possibly related" means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- Suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

This definition could include an unanticipated adverse device effect, any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects (21 CFR 812.3(s)).

7.4.2 UNANTICIPATED PROBLEM REPORTING

The investigator will report unanticipated problems (UPs) to the reviewing Institutional Review Board (IRB). The UP report will include the following information:

- Protocol identifying information: protocol title and number, PI's name, and the IRB project number;
- A detailed description of the event, incident, experience, or outcome;
- An explanation of the basis for determining that the event, incident, experience, or outcome represents an UP;
- A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the UP.

To satisfy the requirement for prompt reporting, UPs will be reported using the following timeline:

- UPs that are serious adverse events (SAEs) will be reported to the within 10 working days of the investigator becoming aware of the event.
- Any other UP will be reported to the IRB at the next continuing review.

An investigator shall submit to the reviewing Institutional Review Board (IRB) a report of any unanticipated adverse device effect occurring during an investigation as soon as possible, but in no event later than 10 working days after the investigator first learns of the effect (21 CFR 812.150(a)(1)).

8 STATISTICAL CONSIDERATIONS

8.1 STATISTICAL HYPOTHESES

There were no hypotheses.

8.2 SAMPLE SIZE DETERMINATION

The sample size of N=18 was selected as a feasible target for a study that was exploratory in nature. A formal power analysis was not conducted. The primary outcome was peak sacral pressure.

8.3 STATISTICAL ANALYSES

8.3.1 GENERAL APPROACH

Continuous data will be reported as mean and standard deviation if normally distributed and median and interquartile range if non-normally distributed. Assumption of normal distribution will be assessed.

Categorical data will be reported as counts and percentages.

No analyses involving covariates is planned.

Paired t-tests will be used to assess for differences between test conditions.
Significance is set at $p<0.05$.

A Holm-Bonferroni correction will be used to control Type I error.

8.3.2 ANALYSIS OF THE PRIMARY EFFICACY ENDPOINT(S)

Peak sacral pressure (mm Hg) is the primary outcome. Two averages for each of the four test conditions will be analyzed (Minutes 1-3 (Min_{1-3}) and 6-8 (Min_{6-8})). These averages capture pressure during two different 5 minute cycles, when conceivably, sacral pressure would differ.

Paired t-Tests will compare the beds at each head of bed position for each time point (4 paired t-Tests). A Holm-Bonferroni correction will be used to control Type I error.

8.3.3 SAFETY ANALYSES

There were no planned safety analyses. There were no known risks associated with the intervention under investigation.

9 SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

9.1 REGULATORY, ETHICAL, AND STUDY OVERSIGHT CONSIDERATIONS

9.1.1 INFORMED CONSENT PROCESS

9.1.1.1 CONSENT/ASSENT AND OTHER INFORMATIONAL DOCUMENTS PROVIDED TO PARTICIPANTS

Consent forms describing in detail the study intervention, study procedures, and risks are given to the participant and written documentation of informed consent is required prior to starting intervention/administering study intervention.

9.1.1.2 CONSENT PROCEDURES AND DOCUMENTATION

Informed consent is a process that is initiated prior to the individual's agreeing to participate in the study and continues throughout the individual's study participation. Consent forms will be Institutional Review Board (IRB)-approved and the participant will be asked to read and review the document. The investigator will explain the research study to the participant and answer any questions that may arise. A verbal explanation will be provided in terms suited to the participant's comprehension of the purposes, procedures, and potential risks of the study and of their rights as research participants. Participants will have the opportunity to carefully review the written consent form and ask questions prior to signing. The participants should have the opportunity to discuss the study with their family or surrogates or think about it prior to agreeing to participate. The participant will sign the informed consent document prior to any procedures being done specifically for the study. Participants must be informed that participation is voluntary and that they may withdraw from the study at any time, without prejudice. A copy of the informed consent document will be given to the participants for their records. The informed consent process will be conducted and documented in the source document (including the date), and the form signed, before the participant undergoes any study-specific procedures. The rights and welfare of the participants will be protected by emphasizing to them that the quality of their medical care will not be adversely affected if they decline to participate in this study.

9.1.2 STUDY DISCONTINUATION AND CLOSURE

This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party to study participants, investigator, and regulatory authorities. If the study is prematurely terminated or suspended, the Principal Investigator (PI) will promptly inform study participants, the Institutional Review Board (IRB), and sponsor and will provide the reason(s) for the termination or suspension. Study participants will be contacted, as applicable, and be informed of changes to study visit schedule.

Circumstances that may warrant termination or suspension include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to participants
- Demonstration of efficacy that would warrant stopping
- Insufficient compliance to protocol requirements
- Data that are not sufficiently complete and/or evaluable
- Determination that the primary endpoint has been met
- Determination of futility

Study may resume once concerns about safety, protocol compliance, and data quality are addressed, and satisfy the IRB.

9.1.3 CONFIDENTIALITY AND PRIVACY

Participant confidentiality and privacy is strictly held in trust by the participating investigators, their staff, and the sponsor(s) and their interventions. Therefore, the study protocol, documentation, data, and all other information generated will be held in strict confidence.

All research activities will be conducted in as private a setting as possible.

Representatives of the Institutional Review Board (IRB) may inspect all documents and records required to be maintained by the investigator for the participants in this study.

The study participant's contact information will be securely stored for internal use during the study. At the end of the study, all records will continue to be kept in a secure location for as long a period as dictated by the reviewing IRB.

Study participant research data, which is for purposes of statistical analysis and scientific reporting, will be stored on host institution approved cloud based storage. Individual participants and their research data will be identified by a unique study identification number. Access to participant information and research data is limited to members of the study team and institutional IRB staff. Members of the study team are defined as those listed on the IRB protocol.

9.1.4 DATA HANDLING AND RECORD KEEPING

9.1.4.1 DATA COLLECTION AND MANAGEMENT RESPONSIBILITIES

Data collection is the responsibility of the clinical trial staff at the site under the supervision of the site investigator. The investigator is responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported.

All source documents should be completed in a neat, legible manner to ensure accurate interpretation of data.

Participant age, sex, height, and weight will be recorded on paper forms and transcribed into excel.

Pressure data will be recorded electronically by the pressure mapping system and transcribed into excel.

9.1.4.2 STUDY RECORDS RETENTION

Study documents will be retained for a minimum of 6 years after the last participant is enrolled in accordance with guidance from the local IRB.

9.1.5 PROTOCOL DEVIATIONS

A protocol deviation is any noncompliance with the IRB approved protocol. The noncompliance may be either on the part of the participant, the investigator, or the study site staff. As a result of deviations, corrective actions are to be developed by the site and implemented promptly.

It is the responsibility of the site investigator to use continuous vigilance to identify and report deviations to the reviewing Institutional Review Board (IRB) per their policies. The site investigator is responsible for knowing and adhering to the reviewing IRB requirements.

9.1.6 CONFLICT OF INTEREST POLICY

The independence of this study from any actual or perceived influence, such as by the pharmaceutical industry, is critical. Therefore, any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the design and conduct of this trial. The location where the study is executed has established policies and procedures for all study group members to disclose all conflicts of interest and will establish a mechanism for the management of all reported dualities of interest.

9.2 ABBREVIATIONS

AE	Adverse Event
CFR	Code of Federal Regulations
DHHS	Department of Health and Human Services
GCP	Good Clinical Practice
GLP	Good Laboratory Practices
HIPAA	Health Insurance Portability and Accountability Act
IRB	Institutional Review Board
OHRP	Office for Human Research Protections
PI	Principal Investigator
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SOA	Schedule of Activities
UP	Unanticipated Problem
US	United States