ISRCTN66819676 https://doi.org/10.1186/ISRCTN66819676

Ultrasound monitoring of tissue changes in patients at risk of developing pressure ulcers: an exploratory study

Submission date	Recruitment status	[X] Prospectively registered
25/09/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/04/2007	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
07/03/2017	Skin and Connective Tissue Diseases	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title

Ultrasound monitoring of tissue changes in patients at risk of developing pressure ulcers: an exploratory study

Study objectives
A Pressure Ulcer (PU) is defined as an area of localised damage to the skin and underlying tissue caused by pressure, shear, friction or a combination of these. PUs commonly occur over bony prominences on the lower half of the body, but they can occur at any site. The two most commonly affected areas are the sacrum and the calcaneus.

Null hypothesis: In a group of patients admitted to an acute care hospital, there is no relationship between the presence of tissue damage under the skin, identifiable by ultrasound scanning, and the subsequent development of PUs where there is definite disruption of the skin.

Alternative hypothesis: In a group of patients admitted to an acute care hospital, there is a relationship between the presence of tissue damage under the skin, identifiable by ultrasound scanning, and the subsequent development of PUs where there is definite disruption of the skin.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Office for Research Ethics Committees in Northern Ireland (ORECNI), September 2006

Study design
Prospective cohort feasibility study

Primary study design
Observational

Study type(s)
Screening

Health condition(s) or problem(s) studied
Pressure ulcers (PUs)

Interventions
The seating interface and both heels of inpatients at the Royal Hospitals will be scanned by a trained researcher using the EPISCAN 1-200 (LongPort, Inc. [USA]) High Frequency Ultrasound Scanner (HFUSS). A daily backup of data will be made on DVD.

The HFUSS is used to detect the presence or absence of oedema or tissue damage below the skin. The scans will be classified later by an independent assessor, who is blind to the clinical assessment. The scans will be classified into the following four distinct categories:
1. Normal scan - no sign of PU development
2. Pockets of subcutaneous oedema
3. Strips of dermal damage and increased subcutaneous damage
4. Sub-epidermal inflammation, strips of dermal damage and major subcutaneous damage

The images for analysis will be stored in digital form. These images consist of a set of numbers that correspond to echo amplitudes at a specific pixel location. The digital information can be stored conveniently in the electronic memory on the EPISCAN ultrasound scanner or on a

magnetic or optical medium without degrading the images over time. The retrieved image information is saved as a standard 512k bitmap (BMP) file and the stored images used for analysis are identical to the original images. The most important advantage of digitisation is that it makes digital image processing of echo information possible, for example, using built-in software on the scanner to perform fractal analysis, the digital echo information can be analysed. This is a method to quantify variations in tissue texture at different anatomical sites. Available commercial programs, such as those that perform Fast Fourier Transformation, can also be utilised to perform analysis of the ultrasound frequencies in the echoes. The analyses using these quantification techniques will be explored using the data from this study.

Potential co-variates:
Additional variables, which are identified as potential co-variates for the development of PUs, will also be obtained. Using an accepted rule of thumb, in which there are at least 10 participants per variable, the calculated sample size is adequate to assess the following potential co-variates and enter them into the analyses:
1. Demographics: age, gender, ward
2. Smoking status
3. Co-morbidities, e.g. vascular-related disorder, diabetes
4. Faecal incontinence - the presence or absence of faecal incontinence will be recorded.
5. If surgery, type of surgery and duration of surgery (min)
6. Malnutrition Universal Screening Tool (MUST) - this screening tool is used to identify those who are at risk of malnutrition. The three-item tool includes information about the participants body mass index, whether or not there was planned weight loss, and presence of acute illness. Risk of malnutrition is categorised into low, medium or high.
7. Braden Scale for Predicting Pressure Sore Risk - this summated rating scale consists of six subscales (sensory perception, moisture, activity, mobility, nutrition and friction and shear), each rated on a 1 to 3 or 1 to 4 categorical scale based on severity, with a total score ranging from 6 to 23. A total score of 12 or less means an individual is at high risk for PU development. Scores of 13 to 14 refer to moderate risk and 15 to 16 for low risk if the individual is less than 75 years of age or scores of 15 to 18 for those over the age of 75. The scale has high sensitivity, but only moderate specificity and predictive validity.
8. Skin condition including clinical signs of normal, blanching and non-blanching erythema

The majority of the above variables are recorded in the medical/nursing notes as part of routine clinical practice.

Recruitment and assessment procedures:
During the initial visit, the Clinical Research Nurse (CRN) will give the patients an information sheet and ask them to participate in this study. The CRN will not approach those patients who are not willing to participate again. Following written informed consent from patients willing to participate, information for all of the additional variables listed above (e.g., date of birth, gender, ward, co-morbidities, etc) will be extracted from each participants medical record or through examination by the CRN. All participants admitted into the study will have their first ultrasound scan and clinical assessment performed as soon as possible, but not later than 48 hours after admission and preoperatively. The CRN and researcher conducting the scans will work alongside the clinical ward staff and conduct the clinical and ultrasound assessments simultaneously. Scanning will take place during the participants normal repositioning schedule to ensure that they are not unduly inconvenienced. Participants will also be scanned before and after surgery (if applicable) and everyday until discharge from the acute care ward (approximately five to nine days). Based on a previous study, the scanning protocol will take five to ten minutes.

Scanning protocol:
One objective of the study is to establish a standardised protocol for scanning the heels and the seating interface such that reliable, high-quality scans are obtained. During data collection, the scanner will be transported on a trolley to the participant on the wards. The ceramic polymer handset will be filled with distilled water, and a rubber membrane stretched over the aperture, ensuring no air bubbles are caught beneath it. With the participants permission, they will be moved into an appropriate position, for scanning the heels and seating interface, ensuring that the patients dignity and comfort is maintained at all times. The areas to be scanned will be marked with a permanent marker and the direction of the scan marked with an arrow (Table 1, below). Coupling gel will be applied to the skin area and the membrane-covered probe will be held vertically and placed on to the skin area to be scanned such that it is not placed over a tendon or blood vessel, to avoid the appearance of artefacts in the image. Scanning will be controlled from the keyboard, probe button or footswitch. Operation will commence at a default standard setting, but may be changed by the operator to optimise the scan image. These settings will be saved and used again in subsequent scanning. Once a good image has been obtained, scanning will stop; the patient will be repositioned and thanked for their participation.

Table 1. Scanning protocol
If skin is intact on left heel, take following HFUS images:
1. Posterior calcaneous (heel bone)
2. Lateral malleolus
3. Medial malleolus
If skin is intact on right heel, take following HFUS images:
1. Posterior calcaneous
2. Lateral malleolus
3. Medial malleolus
If skin is intact on seating interface, take HFUS image of:
1. Coccyx
2. Left ischial tuberosity
3. Right ischial tuberosity

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Presence or absence of a PU (more than or equal to grade two) after baseline assessment and before discharge. Previous work has demonstrated that Clinical Research Nurses are able to identify and record the presence of a PU (more than or equal to grade two) in a consistent and reliable manner, and that initial training and clinical skill is maintained over time.

Key secondary outcome(s))
Development of non-blanchable erythema of intact skin (grade one [b] PU), an important independent predictor of Grade two PU development, increasing the odds approximately four to six-fold. This outcome will be used to monitor the sub-group of participants who, on entry to the study, did not present with any visible signs of pressure damage consistent with a grade one (b) PU.

Completion date

09/12/2007

Eligibility

Key inclusion criteria
1. Inpatients admitted to the acute wards for vascular disease
2. Written informed consent to participate
3. Intact skin on one or more areas to be scanned (seating interface and both heels)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
All

Key exclusion criteria
Existing pressure damage of more than or equal to Grade two visible on their skin (including blisters, abrasions, and ulcers where skin loss is present) on both heels and the seating interface.

Date of first enrolment
04/06/2007

Date of final enrolment
09/12/2007

Locations

Countries of recruitment
United Kingdom

Northern Ireland

Study participating centre
University of Ulster
Newtownabbey
United Kingdom
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Sponsor information

Organisation
Department for Employment and Learning (UK) - Strategic Priority Fund

ROR
https://ror.org/05w9mt194

Funder(s)

Funder type
Government

Funder Name
Department for Employment and Learning (UK) - Strategic Priority Fund

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes