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The number of heel pressure ulcers amongst patients on an orthopaedic ward who wear Prevalon boots or alternative heel protection over a 10 day period

Submission date
31/10/2017

Recruitment status
Stopped

Registration date
04/12/2017

Overall study status
Stopped

Last Edited
13/11/2018

Condition category
Injury, Occupational Diseases, Poisoning

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
A pressure ulcer, also known as pressure sore, is a sore that occurs when a high amount of pressure breaks down the skin. Successful pressure ulcer prevention requires focus upon several aspects of care including the identification of risk of pressure damage, assessment and care of the skin, attention to nutrition along with repositioning and pressure redistributing support surface use to reduce mechanical loading of the skin and soft tissues. The 2014 International Pressure Ulcer Guidelines reports upon specific interventions to reduce the likelihood of heel pressure ulcers given the common occurrence of severe pressure ulcers at this anatomical location. In the guidelines focus is placed upon the appropriate use of heel suspension devices that aim to 'float' the heel so that no mechanical load (force or pressure) is exerted upon this small surface area. While totally removing load from the heel is recommended this practice was not the only approach to heel pressure ulcer prevention noted in the guidelines with the use of prophylactic dressings at the heel also proposed as an effective strategy. There are a wide range of heel suspension devices and prophylactic dressings that could be used to protect the heel including; pillows, foam cushions, gel pads, multi-layer dressings and heel protector boots made either from foam or with air-filled cells. The limited clinical evidence indicates that the use of heel suspension devices reduced heel ulcer incidence compared with standard care however there were no direct comparisons between alternative heel suspension devices. The aim of this pilot study is to compare the incidence of heel pressure ulcers among orthopaedic in-patients allocated either foam based heel protectors (Prevalon™ Heel Protector, Sage Products Inc) or the standard pressure ulcer prevention used by the ward (SPUP), to both heels while resting in bed.

Who can participate?
Adults aged 18 and older who are vulnerable to developing a pressure ulcer on their feet.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive the

prevalon heel protector which they wear for ten days. Those in the second group receive the standard level of care. Participants are followed up to assess the incidence of heel pressure ulcers and compare outcomes in each group.

What are the possible benefits and risks of participating?
There may be no direct benefit to the patient, however the patient will be seen daily by a research nurse and/or research podiatrist who have expertise in the area of pressure injury. Information learned during this study may benefit patients at risk of pressure damage in the future. There are no direct risks with participating.

Where is the study run from?
Welsh Wound Innovation Centre (UK)

When is the study starting and how long is it expected to run for?
May 2015 to December 2018

Who is funding the study?
Sage Products, LLC (under Stryker) (UK)

Who is the main contact?
Mrs Nicola Ivins

Contact information

Type(s)
Scientific

Contact name
Mrs Nicola Ivins

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Protocol No WWIC/2016/07

Study information

Scientific Title
The incidence of heel pressure ulcers among orthopaedic patients who wear Prevalon boots or alternative heel protection: Exploratory study

Study objectives
The aim of this study is to investigate the effectiveness of Prevalon Boots when used to prevent heel pressure injury among orthopaedic hospital patients and to determine the effectiveness of the Prevalon Heel Protector in the prevention and resolution of heel pressure damage compared with the Standard Pressure Ulcer Prevention used by the ward.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Wales REC 4, 14/06/2017, ref: 17/WA/0138

Study design
Pilot randomised controlled single-centre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format. Please contact Nicola Ivins nicky.ivins@wwic.wales to request a patient information sheet.

Health condition(s) or problem(s) studied
Pressure ulcer

Interventions
This is a randomised controlled study (RCT) to investigate the effectiveness of Prevalon Boots when used to prevent heel pressure injury among orthopaedic hospital patients. Willing patients who meet the inclusion and exclusion criteria provide consent and assessed in line with standard care. All prticipants included in the pilot study are randomised to receive either Prevalon boots or standard of care pressure ulcer prevention used by the ward, on an equal basis.

Patients in each arm of the study receive 10 days of treatment and follow-up assessments of their heels. Those who are randomly allocated to receive the Prevalon heel protector group receive the Prevalon Heel protector and wear it on each foot for ten days. Follow-up patient visits are recorded daily. These consist of photographs of both heels and CRF completion.

Intervention Type
Device

Primary outcome measure
1. Incidence of new heel pressure damage is measured assessing the surrounding skin from the photographs at baseline,days one, two, three, four, five, six, seven, eight, nine and 10
2. Resolution of category I heel pressure damage is measured conducting an assessment of the surrounding skin using the photograph of the patients heels. The assessor of the photographs will be blinded to the treatment arms of the patients

Secondary outcome measures
1. Patient comfort is measured by asking the patients questions about their experience at baseline (prior to randomization), day five, and day 10
2. Patient acceptance of the heel protectors is measured by asking questions about the patient's experience at baseline (prior to randomization), day five, and day 10
3. Staff acceptance of the heel protectors is measured by asking questions about the staff's experience at baseline (prior to randomization), day five, and day 10

Overall study start date
31/05/2015

Completion date
31/12/2018

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. Over 18 years old
2. In-patient within designated orthopaedic ward
3. No visible heel pressure damage of category I heel ulcer only
4. Considered vulnerable to developing pressure ulcers based on pressure ulcer risk assessment score and mobility or activity restrictions
5. Able to provide informed consent
6. No lower limb amputations
7. Ankle-brachial pressure index (ABPI) between 0.8 and 1.3 at baseline

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Under 18 years old
2. Visible heel pressure damage (category II and above)
3. Not at risk of developing pressure ulcers
4. Unable to provide informed consent
5. Lower limb amputation
6. ABPI under 0.8 or above 1.3 at baseline
7. Patients who have participated in a clinical trial on wound healing within the past month
8. Patients with a known history of non-adherence with medical treatment

Date of first enrolment
01/11/2017

Date of final enrolment
18/10/2018

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Welsh Wound Innovation Centre
Rhodfa Marics
Ynysmaerdy
Pontyclun
Rhondda Cynon Taf
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CF72 8UX

Sponsor information

Organisation
Sage Products, LLC (now under Stryker)

Sponsor details
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Cary
United States of America
60013

Sponsor type
Industry

ROR
https://ror.org/043affe91

Funder(s)

Funder type
Industry

Funder Name
Sage Products, LLC (under Stryker)

Results and Publications

Publication and dissemination plan
Planned to publish the results in a high-impact peer reviewed journal.

Intention to publish date
30/12/2018

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No