ISRCTN85296908 https://doi.org/10.1186/ISRCTN85296908

Heel protection for pressure ulcer prevention: from prehospital patient care to discharge

Submission date
12/03/2013

Recruitment status
No longer recruiting

Registration date
22/04/2013

Overall study status
Completed

Last Edited
17/12/2020

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Since 2007, patient safety issues which include pressure ulcers prevention are on top of the Swedish healthcares agenda. Research has shown that the incidence of hospital-acquired pressure ulcers on the sacrum (the large bone at the base of the spinal cord) has decreased, probably due to the increase of use of pressure ulcers prevention mattresses. However, the incidence of hospital-acquired pressure ulcers on the heels is still present.
Pressure ulcers cause suffering for the patient and considerable costs for health care. Pressure damage can occur quickly (within hours), depending on the individual patient's risk factors and it is important that preventive actions will start as soon as possible. That can already start in ambulances. Ambulances in Sweden are equipped with conventional stretchers (without pressure relief function) and the length of transport may vary from a few minutes and hours. No study, either international or national, has been done on the development of pressure ulcers across the continuum of care, from the ambulance to the hospital. To our knowledge, no research has so far identified the best method to prevent this kind of pressure ulcers. The aim of the study is to investigate the effects of an early treatment (Heelift heel pressure ulcers prevention boot) on hospital-acquired heel pressure ulcers.

Who can participate?
Patients over 70 years of age, with neurological symptoms or reduced general condition, transferred by ambulance to the emergency department will be invited to participate in this study.

What does the study involve?
Patients will be randomly allocated to one of two groups: the intervention group or the control group.
Patients in the intervention group will receive a heel pressure ulcers prevention boot on both heels. This prevention boot will be used during the whole hospital stay (emergency department, ward). At the end of the hospital stay, the patients will be asked to evaluate the use of the prevention boot, regarding usefulness, comfort and acceptance. Patients in the control group will receive standard pressure ulcers prevention care. Both groups of patients will have their heels assessed for pressure ulcers regularly.

What are the possible benefits and risks of participating?
The patient's level of risk for development of pressure ulcers will be assessed. Patients will also have their heels assessed for pressure ulcers regularly during their hospital stay. These assessments will take place in the ambulance, in the emergency department and throughout the entire hospital stay.
There will no risks to the patients. Participation in this study will not delay any need of medical care.

Where is the study run from?
The study is run from the following study sites: the ambulance care in Uppsala County Council, Uppsala University Hospital, the ambulance care in County Council of Värmland and Karlstad Central Hospital (Sweden).

When is the study starting and how long is it expected to run for?
The study started in May 2011 and is expected to be finished in April 2013.

Who is funding the project?
This study is funded by Uppsala University Hospital, Karlstad University, Uppsala County Council, Varmland County Council and Uppsala-Örebro Regional Research Council (Sweden).

Who is the main contact?
Principal Investigator: Asa Muntlin Athlin, asa.muntlin@pubcare.uu.se
Research Site Manager, County Council of Värmland: Carina Baath

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Heel protection for pressure ulcer prevention: from prehospital patient care to discharge. A randomized controlled trial in two county councils in Sweden.

Study objectives
The overall aim of the study is to investigate the effects of an early intervention (Heelift) on incidence of hospital-acquired heel pressure ulcers.

Research questions:
1. What are the effects of an early intervention (Heelift heel pressure ulcers prevention boot) on incidence of hospital-acquired heel pressure ulcers?
2. Which predictors for heel pressure ulcers can be determined?
3. How do patients perceive the use of the Heelift heel pressure ulcer prevention boot, regarding usefulness, comfort and acceptance?

The hypothesis is that an early intervention, the use of Heelift heel pressure ulcers prevention boot, decrease the incidence of hospital-acquired heel pressure ulcers compared to standard care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Ethical Review Board, Uppsala, Sweden. Dnr 2011/049

Study design
Multicentre randomised controlled intervention study. Block-randomisation according to study sites and sample groups.

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Heel pressure ulcers

Interventions
Intervention: Heelift heel pressure ulcers prevention boot. Regularly pressure ulcer assessments and risk assessments. Time: From prehospital care to discharge.

Control: standard care regarding prevention of pressure ulcers. Regularly pressure ulcer assessments and risk assessments. Time: From prehospital care to discharge.

Follow-up: In the event of an in-hospital acquired heel pressure ulcer, assessment and treatment of the heel pressure ulcer will be recorded until healing.

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Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Incidence of hospital-acquired heel pressure ulcers, classified according to European Pressure Ulcer Advisory Panel (EPUAP), category 1-4 (1= Non-blanchable redness of intact skin, 4= Full thickness tissue loss (muscle/bone visible).

Key secondary outcome(s))
At discharge:
1. Patients perceptions of using Heelift, regarding usefulness and comfort. Measurement: Yes /No/Cannot tell
2. Patients perceptions of acceptance of using Heelift. Measurement: Yes/No/Cannot tell

Completion date
30/04/2013

Eligibility

Key inclusion criteria
1. Patients from the County Council of Uppsala admitted to Uppsala University Hospital (Sweden) and patients from the County Council of Varmland admitted to Karlstad General Hospital (Sweden) will be included in the study.
2. Male/female patients, over 70 years of age
3. With neurological symptoms or reduced general condition transferred with ambulance to the emergency department

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Key exclusion criteria
Patients in need of life-saving treatment

Date of first enrolment
01/05/2011

Date of final enrolment
30/04/2013

Locations

Countries of recruitment
Sweden

Study participating centre
Department of Emergency Care
Uppsala
Sweden
75185

Sponsor information

Organisation
Etac Sverige AB (Sweden)

Funder(s)

Funder type
Research council

Funder Name
Uppsala-Örebro Regional Research Council (Sweden) ref: RFR-218661, RFR-138231

Funder Name
Uppsala County Council (Sweden) ref: LUL- 191821

Funder Name
Karlstad County Council (Sweden) ref: LIV FOU 214811, LIV FOU 169261

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?
Results article	results	14/11/2016	17/12/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes