

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

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 22/04/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 17/12/2020	<b>Condition category</b> Skin and Connective Tissue Diseases	<input type="checkbox"/> 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 healthcare 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](mailto: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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Prevention

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

## **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.

Joint/Scientific contact details:

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## **Intervention Type**

Other

## **Phase**

Not Applicable

## **Primary outcome measure**

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)).

## **Secondary outcome measures**

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

## **Overall study start date**

01/05/2011

## **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

**Age group**

Senior

**Sex**

Both

**Target number of participants**

304

**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)

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Industry

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## 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

**Publication and dissemination plan**  
Not provided at time of registration

**Intention to publish date**

**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?
<a href="#">Results article</a>	results	14/11/2016	17/12/2020	Yes	No

