Comfort and Safety Study of Electrical Stimulation in Prevention of Decubitus.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24045

Source
Nationaal Trial Register

Brief title
Electrical stimulation for decubitus prevention

Health condition

Decubitus

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: European Union

Intervention

Outcome measures

Primary outcome

The primary objectives of this study are:

1. Will there be any adverse events, due to the electrical stimulation?

2. Are the sock and the electrical stimulation comfortable for the patient?

Secondary outcome

N/A

Study description

Background summary

Background of the study:

Decubitus ulcers represent a major burden of sickness and reduced quality of life for patients and their carers. In general hospital Medisch Spectrum Twente, Holland, the incidence of decubitus developed on the Intensive Care was 123 patients in the year 2008. This is 18% of the total number of patients admitted on the Intensive Care, excluding the patients who have decubitus ulcers at the moment of admitting. These patients developed decubitus grade 1 – 4 despite all kind of precautions taken, like special mattresses, frequently turning patients to release pressure and nutritional status. The total costs of decubitus is estimated between 84.9 miljon euro and 1.9 biljon euro in Holland alone. There have been several studies that showed a possible positive effect of electrical stimulation on wound healing. One of the working principles is increasing blood flow. This could mean that by giving frequent electrical stimulation on the foot and lower leg, the blood flow increases and thereby the amount of oxygen to the skin. Our hypothesis is that this will help to reduce the risk of decubitus on the heel. Before we can investigate this, we will do a comfort and safety study of the sock and electrical stimulation.

Objective of the study:

The primary objectives of this study are:

1. Will there be any adverse events, due to the electrical stimulation?

2. Are the sock and the electrical stimulation comfortable for the patient?

Study design:

The study design is a prospective intervention study. The socks will be worn on both feet to look at adverse events or discomfort of the sock. The right foot of the patient will get electrical stimulation to look at adverse events or discomfort of the electrical stimulation.

Study population:

Patients who are admitted to the vascular surgery ward (C3) of Medisch Spectrum Twente and are expected to be admitted for at least 3 days, excluding weekend days.

Intervention:

The patient will wear both socks 1 hour a day, for 3 days. The right foot will receive the electrical stimulation. The total time of wearing the sock and receiving electrical stimulation will be 3 hours for each patient.

Main study parameter/endpoint is the number of occurrences of any kind of discomfort or adverse event due to the sock or electrical stimulation.

Study objective

Electrical stimulation on the foot and lower
leg will increase the blood flow and thereby the amount of oxygen to the skin. Our overall hypothesis is that this will help to reduce the risk of decubitus on the heel. The specific hypothesis for this comfort and safety study is that the electrical stimulation is safe and not uncomfortable.

Study design

The patient will wear both socks 1 hour a day, for 3 days. The right foot will receive the electrical stimulation. The total time of wearing the sock and receiving electrical stimulation will be 3 hours for each patient.

Intervention

The patients will wear a sock on each foot that contains electrodes for electrostimulation. The right foot will be stimulated three times one hour in three days. The left foot will only wear the sock for the same amount of time.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients who are admitted to the vascular surgery ward (C3) of Medisch Spectrum Twente;

2. Expected stay on the vascular surgery ward for at least 3 days, excluding weekend days.

Exclusion criteria

1. Decubitus ulcer grade 1 – 4 on the heel;

2. Ulcer or surgical wound at the lower leg;

3. Amputation of one or both legs;

4. Inability to wear the sock;

5. Dark skin;

6. Other exclusion criteria included any of the following medical conditions for which electrical stimulation is
contraindicated { Houghton PE, Campbell KE; 2001}:

A. Ventricular arrhythmia;

B. Atrial fibrillation;

C. Cardiac pacemaker;

D. History of deep radiation therapy within the local region;

E. Superficial metal ions or metal implants near the area;

F. Pregnancy.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2010
Enrollment:	25
Type:	Actual

Ethics review

Positive opinion

Date:	23-03-2010
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2130
NTR-old	NTR2254
Other	METC Medisch Spectrum Twente : P10-15
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A