Comfort and Safety Study of Electrical Stimulation in Prevention of Decubitus

Published: 20-05-2010
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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?

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cornification and dystrophic skin disorders
Study type	Interventional

Summary

ID

NL-OMON34716

Source
ToetsingOnline

Brief title
Comfort and Safety of Electrical Stimulation in Decubitus

Condition

- Cornification and dystrophic skin disorders

Synonym
Decubitus

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: Europese Unie in het 6e kaderproject. Projecttitel: Lidwine

Intervention

Keyword: Decubitus, Electrical stimulation, Prevention

Outcome measures

Primary outcome

Main study parameter/endpoint is the number of occurrences of any kind of

discomfort or adverse event due to the sock or electrical stimulation.

Secondary outcome

None

Study description

Background summary

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.

Study objective

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.

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.

Study burden and risks

Looking at the different kind of electrical stimulation that is already used in the hospital (eg. TENS), the type of electrical stimulation we are going to use is expected to be harmless, with no side effects.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

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

Exclusion criteria

Decubitus ulcer grade 1 - 4 on the heel
Ulcer or surgical wound at the lower leg
Amputation of one or both legs
Inability to wear the sock
Dark skin
Other exclusion criteria included any of the following medical conditions for which electrical stimulation is contraindicated { Houghton PE, Campbell KE; 2001}:
Ventricular arrhythmia
Atrial fibrillation
Cardiac pacemaker
History of deep radiation therapy within the local region
Superficial metal ions or metal implants near the area
Pregnancy

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped

Start date (anticipated):	31-05-2010
Enrollment:	25
Type:	Actual

Medical products/devices used

Generic name:	Sock for electro stimulation
Registration:	No

Ethics review

Approved WMO Date:	20-05-2010
Application type:	First submission
Review commission:	METC Twente (Enschede)

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
CCMO	NL31370.044.10