Effectiveness Study of Electrical Stimulation in Prevention of Decubitus

Published: 07-10-2010
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The primary objective of this study is to investigate the effectiveness of electrical stimulation in reducing the incidence of decubitus ulcers on the heel in Intensive Care patients

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

Summary

ID

NL-OMON34994

Source
ToetsingOnline

Brief title
Effectiveness 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 subsidie in het kader van het 6e kader programma.

Intervention

Keyword: Decubitus, Electrical stimulation, Prevention

Outcome measures

Primary outcome

Main study parameter/endpoint is the incidence of decubitus on the heel in participating patients and the difference in incidence of decubitus between treatment and control leg.

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 (18%). 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.

Study objective

The primary objective of this study is to investigate the effectiveness of electrical stimulation in reducing the incidence of decubitus ulcers on the heel in Intensive Care patients

Study design

The study design is a prospective, within patients randomised controled pilot study with randomisation between both legs of the patient. The socks will be worn on both feet but only one foot will get electrical stimulation.

Intervention

The treatment group (one leg of the patient) will get electrical stimulation for 1 hour a day. The control group (the other leg of the patient) will wear the sock, but will not get the electrical stimulation.

Study burden and risks

Most of the decubitus ulcers occur at the Intensive Care unit. Getting a decubitus ulcer is often painfull and can result in prolonged stay in the hospital and more visits to the outpatient clinic after discharge. Decubitus gives a reduction in the quality of life for the patient and his carers. It is affecting all age groups and is costly both in terms of human suffering and use of resources. Looking at the different kind of electrical stimulation what 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 and has already been shown to be safe and comfortable. It is possible that electrical stimulation can prevent decubitus by increasing the cappilary blood flow.

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 Intensive Care for at least 48 hours
Braden score < 20

Exclusion criteria

Decubitus ulcer grade 1 - 4 on the heel
Ulcer at the lower leg
Amputation of one or both legs
Difference of more than 25% between both legs in the Ankle Brachial Index
Systolic blood pressure at the foot > 250mmHg
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
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-06-2011
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	Sock for electro stimulation
Registration:	No

Ethics review

Approved WMO

Date:	07-10-2010
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	NL31400.044.10