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

Gepubliceerd: 23-03-2010 Laatst bijgewerkt: 18-08-2022

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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24045

Bron
Nationaal Trial Register

Verkorte titel
Electrical stimulation for decubitus prevention

Aandoening

Decubitus

Ondersteuning

Primaire sponsor: Medisch Spectrum Twente
Overige ondersteuning: European Union

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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?

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-05-2010
Aantal proefpersonen:	25
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	23-03-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A