Effectiveness Study of Electrical Stimulation in Prevention of Decubitus.

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

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...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29627

Bron
NTR

Verkorte titel
Effectiveness of Electrical Stimulation in Decubitus

Aandoening

Decubitus

Ondersteuning

Primaire sponsor: Medisch Spectrum Twente
Enschede
Overige ondersteuning: European Union

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Incidence of decubitus ulcers of the heel.

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 (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.

Objective of the study:

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.

Study population:

Patients who are admitted to the Intensive Care ward of Medisch Spectrum Twente and are likely to stay there for at least 48 hours.

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.

Primary study parameters/outcome of the study:

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.

Doel van het onderzoek

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.

Onderzoeksopzet

Patients will be treated during their stay on the ICU or until a pressure ulcer of grade 1 or higher occurs.

Onderzoeksproduct en/of interventie

The patients will wear a sock on each foot that contains electrodes for electrical stimulation. For each patients it will be randomised which foot receives electrical stimulation for one hour per day. The treatment stops when a pressure ulcer of grade 1 or higher occurs or when the patient is discharged from the Intensive Care.

Details of the electrical stimulation:

1. Frequency: 100 Hz;

2. Pulse width 200 milliseconds;

3. Output current 6 mA.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Expected stay on the Intensive Care for at least 48 hours;

2. Braden score < 20.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

2. Ulcer at the lower leg;

3. Amputation of one or both legs;

4. Difference of more than 25% between both legs in the Ankle Brachial Index;

5. Systolic blood pressure at the foot > 250mmHg;

6. Inability to wear the sock;

7. Dark skin;

8. 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:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-05-2011
Aantal proefpersonen:	50
Type:	Verwachte 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	NL2131
NTR-old	NTR2255
Ander register	METC Medisch Spectrum Twente : P10-16
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A