Topical application of calcipotriol for preventive treatment of hypertrophic scars: a randomized, double-blind, placebo-controlled trial

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

Samenvatting

ID

NL-OMON27742

Bron
NTR

Verkorte titel
N/A

Aandoening

Hypertrophic scars, keloids
Littekenhypertrofie

Ondersteuning

Primaire sponsor: VU University Medical Center, Amsterdam.
This investigation was supported by a grant of the Dutch Burns Foundation and the Cornelis Visser Foundation.
Overige ondersteuning: This investigation was supported by a grant of the Dutch Burns Foundation and the Cornelis Visser Foundation. The ointment packages were provided by Leo Pharma A/S.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Evaluations took place under standardized circumstances at 3 weeks, 3 months and 12 months following surgery and were performed by the same observer (IEW).
During all evaluations, the scar’s clinical aspect was scored as normotrophic (when flat) or hypertrophic (when raised above surrounding skin level). Scoring and measuring was done at 3 cm from the scars lateral and medial extremes.
To quantify the scar’s macroscopic properties, its thickness was measured ultrasonographically at 3 and 12 months postoperative, using a 7,5 MHz-probe (SSD-680 EX/STD, Aloka Co., Ltd., Japan). In order to obtain a reliable image, a gel pad (Aquaflex®, Parker Laboratories Inc., Fairfield, USA) was placed between the probe and the skin. The distance (in mm) between the echogenic stratum corneum and subcutaneous tissue (appearing as a ‘black circle’) was measured. This method has proven to be valuable in the morphological assessment of the skin, but also in distinguishing normal from hypertrophic scars.

Toelichting onderzoek

Achtergrond van het onderzoek

Background.

The epidermis of hypertrophic scars shows histological abnormalities similar to psoriatic lesions. Calcipotriol is widely used for treatment of psoriasis.

Objectives.
To investigate the efficacy of topical application of calcipotriol in preventing hypertrophic scar formation.

Methods.
In a randomized, double-blind, placebo-controlled trial, 35 women were enrolled. The bilateral reduction mammoplasty wound healing model was used. Starting 10 days postoperative, scar-segments were either treated with calcipotriol or placebo, for the total duration of three months. At 3 weeks, 3 months and 12 months postoperative, the scar aspect was scored, its thickness was measured by ultrasound, and punch biopsies were collected for histological

analysis.

Results.
After 3 and 12 months, no significant difference in prevalence of hypertrophic scars was observed between the placebo- and calcipotriol-treated scars. At 3 weeks postoperative, the calcipotriol-treated scars contained significantly more epidermal layers (p=0.017) and proliferating basal keratinocytes (p=0.029). None of the 3-week-old scars without activated keratinocytes became hypertrophic, whereas 48% of the 3-week-old scars that contained activated keratinocytes did (p=0.001). After three months, hypertrophic scars contained more epidermal layers than normotrophic scars (p=0.013).

Conclusions.
Topical application of calcipotriol during the first three months of wound healing did not affect the incidence of hypertrophic scar formation. Contrary to its effects in psoriatic lesions, calcipotriol treatment increased proliferation of keratinocytes and the number of epidermal layers. We observed a strong association between keratinocyte activation and hypertrophic scar formation. These findings contribute to the concept of both dermal and epidermal involvement in the aetiology of hypertrophic scar formation.

Doel van het onderzoek

The epidermis of hypertrophic scars shows histological abnormalities that are similar to psoriatic lesions. Calcipotriol is widely used for treatment of psoriasis. We investigated the efficacy of topical application of calcipotriol in preventing hypertrophic scar formation.

Onderzoeksopzet

Evaluations took place under standardized circumstances at 3 weeks, 3 months and 12 months following surgery and were performed by the same observer (IEW).

Onderzoeksproduct en/of interventie

Ten days following surgery (after reepithelialization had been established), participants received a pair of ointment packages, marked ‘R’ and ‘L’, which were kindly provided by Leo Pharmaceutical Products (Ballerup, Denmark).
These were randomly filled with either calcipotriol 50 ìg/g (Daivonex® in vehicle) or placebo (vehicle only).

Both participant and observer were unaware of the content of the ointment packages. Participants were carefully instructed to apply the content of the package marked ‘R’ with the right hand on the left lateral (LL) and right medial (RM) scars. Accordingly, the content of the package marked ‘L’ had to be applied on the right lateral (RL) and left medial (LM) scars. The

application frequency was twice daily, with a total duration of three months.
To verify our data, participants were questioned during the last evaluation about the way the ointment had been applied. This resulted in a minor adaptation of data in one case, as the ointment had been applied oppositely. Not until the final evaluation of the last participant, the key to the exact content of the packages was revealed and inserted into the data file.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Women aged above 18 years that were planned for bilateral reduction mammoplasty at the University Medical Center of Groningen received written information about the study prior to surgery.

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

Exclusion criteria for participation were current or planned pregnancy in the first year following surgery and postoperative complications (e.g. haematoma, infection).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2002
Aantal proefpersonen:	35
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	09-10-2008
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	NL1427
NTR-old	NTR1486
Ander register	Dossiercode METC AZG : 2000/168
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A