Determining the possible association of skin irritation threshold and hypertrophic scar formation

Published: 27-11-2013
Last updated: 24-04-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON43681

Source
ToetsingOnline

Brief title
Irritation threshold and hypertrophic scars

Condition

- Other condition
- Epidermal and dermal conditions

Synonym
Hypertrophic scar, raised scar

Health condition

littekenhypertrofie van de huid

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Hypertrophic scar, Immunology, Skin irritation threshold, Wound healing

Outcome measures

Primary outcome

The primary study parameter is the IT as determined by visual irritation

grading scale after SLS patch test.

Secondary outcome

The secondary study parameters are IL1a/IL1Ra ratios in the SC, TEWL, erythema

as measured with DermaSpectrometer®, response of PBMC*s to stimulation with

LPS, leukocyte numbers and cytokines in serum.

Study description

Background summary

Preliminary data show that the inflammatory response in wounds which give rise to hypertrophic scars (HTSs) is reduced compared to wounds which result in normal scars. In the general population some individuals have severe inflammatory responses to skin irritants (low skin irritation threshold (IT)), while others react with mild responses or no response at all (high IT).
Our study aims to examine the possible association between high IT (low skin irritation) and HTS formation. We will also examine the possibility to use high IT as a non-invasive prognostic tool for HTS formation.

Study objective

The main objective of our study is to examine whether there is an association between IT (as determined by visual irritation grading scale after SLS patch test) and HTS formation and whether IT is a good predictor for HTS formation. If so then this may be used as a non-invasive tool to predict scar outcome in

terms of HTS formation.
The secondary objectives consist of examining the association of HTS formation with IL1a/IL1Ra ratios in the stratum corneum (SC), PBMC stimulation, peripheral blood leukocyte and cytokine concentrations, trans-epidermal water loss (TEWL) and DermaSpectrometer® erythema measurements after SLS patch testing. The secondary parameters can support our findings with respect to the primary objective.

Study design

We will conduct an observational study with reduction mammoplasty patients. A total of 30 subjects with HTS and 30 subjects with normal scars will be included.
At the first out-patient visit, the scars resulting from the reduction mammoplasties will be scored either hypertrophic or normal by a scar specialist. Peripheral blood will be collected via venipuncture. The SLS patch test will be applied on the upper arm and will be removed 2 days later by the participant.
4 days after the first visit, skin irritation at the patch test site will be scored by means of a visual grading system, erythema is measured with a DermaSpectrometer® and TEWL is measured with a TEWAmeter TM300®. Perifeer bloed wordt afgenomen met een venapunctie. In order to determine the IL1a/IL1Ra ratio at the patch test site, SC fluids will be collected via sebutapes. Null measurements of TEWL, erythema and IL1a/IL1Ra ratio are performed on skin of the opposite upper arm to the patch test. The scars as well as the skin to which the patch has been attached will be photographed in a standardized manner.

Study burden and risks

Participants will be subjected to a completely non-invasive ambulant skin irritation patch test, where a patch with 4 different concentrations of SLS and 1 water control will be applied to the upper arm at time point zero and removed after 2 days, followed by readout of primary and secondary parameters at day 4. Participation in this study will require 2 hospital visits.
The patch test is a well established method of determining skin irritation that can cause minor discomfort e.g. transient erythema.
SC cytokines are collected using sebutape. There are no known risks for the IL1a/IL1Ra collection from SC by using sebutape.
Peripheral blood is collected by venipuncture, which is a very low risk procedure.
If the IT determined by patch testing proves to be a good predictive tool for HTS formation, future surgical patients will benefit from this test, since clinicians will be able to predict HTS formation and possibly interfere early in the process of HTS formation, before it becomes clinically visible.

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

Reduction mammoplasty, at least 3 months post-operative
18 years of age or older
Legally competent
Patient group: scar hypertrophy in at least one of the scars
Control group: all scars have remained normal (flat) during the entire post-operative period

Exclusion criteria

Fitzpatrick photo skin type V
Skin disease, skin lesions
Immunological disorders

Pregnancy/lactation or systemic immunosuppressive treatment during the first two years post-operatively or during the patch test

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-08-2014
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	27-11-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-04-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-10-2015
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-07-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL40722.029.13