Further determining the possible association of skin irritation threshold and hypertrophic scar formation

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Objective: The main objective of our study is to examine whether we can use the IT (as determined by visual irritation grading scale after SLS patch test) to predict HS formation after reduction mammaplasties. The secondary objectives consist of...

Ethical review	Not approved
Status	Will not start
Health condition type	Allergic conditions
Study type	Observational invasive

Summary

ID

NL-OMON51239

Source
ToetsingOnline

Brief title
Irritation threshold and hypertrophic scars-part two

Condition

- Allergic conditions
- Epidermal and dermal conditions

Synonym
hypertrophic scars, skin allergic reaction

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: hypertrophic, irritation, scars, threshold

Outcome measures

Primary outcome

Main study parameters/endpoints:

Primary parameter: IT as determined by visual irritation grading scale after

SLS patch test.

Secondary outcome

Secondary parameters: response of PBMC*s to stimulation with LPS, and cytokines

in serum.

Study description

Background summary

Rationale: Previous research showed an association between irritation threshold (IT) and hypertrophic scar (HS) formation. In this study, we want to further determine this association and examine the possibility to use high IT as a non-invasive prognostic tool for HS formation.

Study objective

Objective: The main objective of our study is to examine whether we can use the IT (as determined by visual irritation grading scale after SLS patch test) to predict HS formation after reduction mammaplasties. The secondary objectives consist of examining the other predictors of HS formation: cytokine secretion upon PBMC stimulation, cytokine levels in serum, after SLS patch testing. These secondary parameters can support our findings with respect to the primary objective.

Study design

Study design: Observational study with invasive measurements.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Patients that are willing to participate in the study will undergo a completely non-invasive ambulant skin irritation patch test. Four 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 1 extra hospital visit, 1 telephone call and 1 online consultation. In previous research, the patch test was found to cause a minor discomfort. It is a well established method of determining skin irritation (transient erythema).
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 HS formation, future surgical patients will benefit from this test, by early interventions to decrease HS formation, or by discouraging patients to undergo certain operations.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Healthy human female volunteers who are prior to undergoing reduction mammoplasties, are 18 years or older and legally competent.

Exclusion criteria

* Fitzpatrick photo skin type IV or higher
* Skin disease, e.g. psoriasis, pemphigus vulgaris etc.
* Skin lesions, tattoos or substantial hair growth on the patch test site
* Pregnancy or lactation during the patch test
* Topical immunosuppressive treatment of the upper arm in the last 7 days before the patch test
* Application of skin lotions or ointments on the upper arm in the last 6 weeks before the patch test
* Abundant exposure of the upper arm to UVR during the patch test
* Systemic antibiotic treatment in the last 2 weeks before the patch test
* Systemic immunosuppressive treatment
* Immunological disorders: infectious disease, immune deficiencies, auto-immune disorders
* Alcohol or drug abuse
* Smoking
* ASA classification 3 or higher
* Simultaneous participation in another clinical study that could interfere with the outcome of this study
* Performing physical activities which cause heavy sweating, sauna, swimming or extreme showers or baths during the patch test

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	62
Type:	Anticipated

Ethics review

Not approved

Date:	20-12-2021
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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	NL76519.099.21