The human body facing and defending from chemical skin allergens reacting by alternative mechanisms: understanding from the molecule to the tissue * an explorative pilot study

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To study the impact of primary keratinocytes isolated of allergic contact dermatitis (ACD) cases on THP-1 cell activation.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Epidermal and dermal conditions
Study type	Observational invasive

Summary

ID

NL-OMON45820

Source
ToetsingOnline

Brief title
Chemical skin allergens reacting by alternative mechanisms

Condition

- Epidermal and dermal conditions

Synonym
contactallergy / contactdermatitis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: eigen budget

Intervention

Keyword: keratinocytes, pathogenesis, terpene hydroperoxides, THP-1 cells

Outcome measures

Primary outcome

Keratinocytes from the biopsies of allergic individuals and controls will be isolated and propagated in vitro. They will be cocultured with the dendritic cell surrogate THP-1 cells and exposed to purified terpene hydroperoxides. As main study parameters/endpoints will be the release of inflammatory mediators and expression of activation markers in and on both types.

Secondary outcome

N/A

Study description

Background summary

Rationale: The aim is to elucidate whether susceptibility factors arising from diseased keratinocytes are implicated in the activation of the innate immune response. In order to investigate this, keratinocytes from subjects with a proven contact allergy (control: healthy subjects) will be harvested from a skin biopsy.

Study objective

To study the impact of primary keratinocytes isolated of allergic contact dermatitis (ACD) cases on THP-1 cell activation.

Study design

Laboratory study with keratinocytes, which will be isolated from biopsies from both cases and healthy controls, and propagated in vitro in the lab (Trier University) * laboratory study with an invasive procedure.

Intervention

Two skin biopsies will be taken from each case, one skin biopsy from each healthy control. For cases, the biopsies will be taken from the skin area on the volar side of both forearms, where on one arm a patch test will be performed with either FM I or FM II, and on the other arm a patch test with only petrolatum. The skin biopsies will be taken on day 3 after the patch tests are applied. For controls, the skin biopsy will be taken from the volar side of an forearm.

Study burden and risks

Duration of participation for cases will be 4 days. A patch test containing either FM I or FM II, depending on their sensitivity, will be applied on the volar aspect of one forearm, with a patch test containing only petrolatum on the other arm, both for 48 hours. At 72 hours the skin biopsies will be takes, one from the elicitation reaction from the FM I/II patch test and one from the petrolatum occluded skin. Each volunteer will have to visit the UMCG two times, once to apply the patch test, and a second time to take the skin biopsies.
For healthy controls, there is one visit to the UMCG in which a biopsy will be taken of healthy skin from the forearm.

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

Case group:
- A proven contact allergy (by previous patch testing at the department of dermatology in the UMCG) to either/both FM I and/or FM II.
- Caucasian female
- Age between 20 and 50 years
- Legal competence;Control group:
- Caucasian female
- Age between 20 and 50 years
- No clinical history of dermatitis reaction to fragranced products
- Legal competence

Exclusion criteria

- Skin-anomalies on the forearm such as active eczema
- Current atopic dermatitis or psoriasis
- The use of immunosuppressive medication during the study or in the four weeks before inclusion (oral corticosteroids, cyclosporine, methotrexate, azathioprine and biologicals)
- Legally incompetent
- Difficulty understanding spoken and written information in Dutch.

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:	Will not start
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO

Date:	07-11-2018
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL65736.042.18