Atopy Patch Test induced TSLP expression in atopic dermatitis skin.

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This is a pilot study with the objective of studying the effect of vaselin on TSLP expression in nonlesional human AD skin.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Epidermal and dermal conditions
Study type	Observational invasive

Summary

ID

NL-OMON36868

Source
ToetsingOnline

Brief title
Atopy Patch Test induced TSLP expression in atopic dermatitis skin.

Condition

- Epidermal and dermal conditions

Synonym
atopic dermatitis (AD), eczema

Research involving
Human

Sponsors and support

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

Intervention

Keyword: atopic dermatitis, atopy patch test, TSLP

Outcome measures

Primary outcome

In vivo: TSLP mRNA expression level (qPCR or quantitative Polymerase Chain Reaction) in cryosections from skin biopsy material (quantitative).

Secondary outcome

Immunohistochemical staining for TSLP protein and other related products in cryosections from skin biopsy material (qualitative; determining presence and localization).

Study description

Background summary

Atopic dermatitis (AD) is an atopic chronic inflammatory skin disease, usually characterised by high levels of circulating IgE and infiltration of skin lesions by immune cells that express a predominant Th2 cytokine pattern. This infiltration with immune cells is much less outside the skin lesions. However, the presence of immune cells in the nonlesional skin makes it immunologically 'pre-activated' compared to healthy control skin. Recently a cytokine called thymic stromal lymphopoietin (TSLP) was discovered that is produced by keratinocytes and seems to play an early role in the induction of allergic inflammation in the skin, both in mice and in humans. In humans, TSLP is detected only in lesional but not in nonlesional AD skin. In healthy human skin, TSLP expression can be induced ex vivo, by allergens, cytokines, micro-organisms and trauma.
Still, little is known about the factors that trigger TSLP expression by keratinocytes in human AD skin or the kinetics thereof.
The atopy patch test (APT) is a human in vivo model for atopic dermatitis. During the APT an allergen (e.g. house dust mite) is patched onto the skin for 24-48 hours, resulting in an eczematous reaction, which is very similar to lesional AD. We have recently shown house dust mite induced expression of TSLP in APT (manuscript in preparation). Some patients had a negative APT during the study, despite an initial positive test during screening. In biopsies from these negative APTs, we did find increased TSLP gene expression, but no TSLP protein expression. This suggests that patch testing in these patients induced activation of the TSLP pathway independent of the allergen activity. Insight into the mechanisms of vaselin (solvent) patch test on TSLP expression will

enable a better controlled interpretation of previous study (protocolnr NL32336.041.10) results, as well as better future interpretation of APT-induced lesional AD skin model results. This is a pilot study with the objective of studying the effect of vaselin patch test on TSLP expression in nonlesional AD skin.

Study objective

This is a pilot study with the objective of studying the effect of vaselin on TSLP expression in nonlesional human AD skin.

Study design

This is a pilot study.
The effect of vaselin on TSLP expression in human nonlesional AD skin (n=5).
a. Biopsies from nonlesional skin (1 biopsy) and 48 hours (1 biopsy) after patch test with vaselin only.
b. TSLP mRNA (qPCR) levels measured in biopsy material. Localization of TSLP expression and other related products (immunohistochemistry) in biopsy sections.

Study burden and risks

Participants will undergo an APT and two skin punch biopsies (4mm diameter) in two sessions. The specified number of biopsies is necessary to carry out sufficient controls. Only the 48 hour time point is chosen for biopsying, to enable TSLP protein detection (as well as TSLP mRNA detection) to ascertain a possible effect and at the same time reduce the number of biopsies as much as possible.
The specified amount of material is necessary to perform the described analyses. There is no direct benefit for participants. Performing a biopsy entails a slight risk of haemorrhage and infection. A small scar at the site of biopsy will gradually fade in colour. An APT will induce erythema and pruritus with sometimes papules, vesicles and blisters. The reaction disappears after 72-96 hours.

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

age 18-70 years
AD
positive APT during previous study (NL32336.041.10 or 10-161 METC UMCU) and local TSLP mRNA (qPCR) and protein expression (immunohistochemistry) detectable in skinbiopsy material from testsite.

Exclusion criteria

- Active AD on the back
- LSS >30
- Not sensitized to aeroallergens, such as house dust mite (demonstrated by a positive Immuno CAP test for these allergens).
- Treatment with systemic corticosteroid or other immunosuppressive medication (such as cyclosporin) within the 4 weeks prior to having the biopsies performed. In addition, weekly use of equal or more than 50 grams of topical corticosteroids class IV or weekly use of equal or more than 100 grams of topical corticosteroids class III.
- Treatment of the biopsy and APT regions not restricted to indifferent topical treatment in the 2 weeks prior
- Exposure of biopsy location to UV sunlicht (e.g. UV-therapy, sunny holiday) in the 2 weeks prior to taking biopsies.

- Use of coumarin derivatives
- Use of antihistamines in the week or days before and during the APT (see patientinformation 'Bijlage 4: Medicatielijst').

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-10-2012
Enrollment:	5
Type:	Actual

Ethics review

Approved WMO

Date:	10-10-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL41110.041.12