Identification of inflammatory mediator profiles associated with dental devices in order to provide leads in detecting an oral allergic reaction.

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Primary: To identify potential diagnostic cytokine profiles for an allergic reaction towards a dental device in patients with symptoms of oral metal allergy. Which might lead to a better understanding of allergic based systemic reaction of oral…

Ethical review	Approved WMO
Status	Pending
Health condition type	Allergic conditions
Study type	Observational invasive

Summary

ID

NL-OMON45591

Source
ToetsingOnline

Brief title
Skingiva Study

Condition

- Allergic conditions
- Skin and subcutaneous tissue disorders NEC

Synonym
Allergy, Type IV hypersensitivity

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Contact dermatitis, Crevicular fluid, Cytokine profile, Dental reconstructive material, Gingiva, Mesoscale, Nickel allergy, Palladiuim allergy, Patch test, Skin

Outcome measures

Primary outcome

* Determine differences in cytokine profiles obtained from gingiva crevicular

fluid samples derived from both test groups.

* Determine correlation of lymphocyte proliferation test/cytokine secretion

test upon in vitro stimulation with metal salts (Ni, Pd) with suspected metal

allergy.

* Determine correlation of skin tape strip secretome with suspected metal

allergy

Secondary outcome

n/a

Study description

Background summary

Skin and oral mucosa (e.g. gingiva, buccal mucosa, palatum) are both fully immunologically competent tissues involved in the induction and effector phase of the immune response. They both function by forming a barrier to harmful environmental factors with the capacity to maintain homeostasis and regulate immune responses when dealing with pathogens. However, clinical observations suggest that these tissues react differently to insults arising from the environment. For example, differences were observed in immune reactions to nickel when comparing skin to oral mucosa. Whereas first nickel exposure via

the skin can result in sensitization, a first oral exposure to nickel e.g. in the form of dental braces has been shown to induce specific tolerance1 where an oral exposure to a person that became allergic to nickel by skin contact can result in an oral and systemic allergic reaction. This would indicate that skin is immune-stimulatory and oral mucosa is tolerogenic at first exposure and suggests a differential role for residential cells (e.g. keratinocytes, fibroblasts and DC) and their cross-talk with immune cells within skin and oral tissue.
However many allergies within the oral cavity have also been reported e.g. nickel and palladium allergy caused by dental restorative materials2,3. An allergic reaction due to an oral exposure to allergens can also often result in systemic reactions, e.g face or foot eczema. This raises the question whether oral or another skin exposure is the cause of those symptoms.
Currently, measurements for diagnostic purposes are indirectly made by patch testing the skin of patients suspected of an allergy towards their metal dental devices. Recently a new method became available (Meso Scale) that opens the possibility to analyze the extremely low concentrations of cytokines within the crevicular fluid within the gingival pocket around de tooth or oral dental device. This will give the opportunity to compare cytokine profiles of skin and mucosal exudate in patients with (systemic) symptoms of oral metal allergy.
With this study we will evaluate the immunological reaction of oral mucosa (gingiva) directly in contact with palladium or nickel based dental devices and compare this to healthy mucosa not directly in contact with palladium or nickel. Furthermore, we aim to compare the oral mucosa immunological reaction with a *gold standard*, the skin patch test (routine diagnostic). This study will identify potential diagnostic cytokine profiles which will provide leads to identifying an oral allergic reaction. The knowledge obtained might in the future lead to the development of a totally new diagnostic approach for the determination of *oral allergy* with systemic symptoms.

Study objective

Primary: To identify potential diagnostic cytokine profiles for an allergic reaction towards a dental device in patients with symptoms of oral metal allergy. Which might lead to a better understanding of allergic based systemic reaction of oral exposure to metals in sensitized patients.

Secondary: To compare the immunological reaction of mucosa in contact with palladium or nickel based dental devices with the cytokine profile obtained from tape stripping of the routine diagnostic skin patch test site. And to re-evaluate the peripheral blood lymphocyte assay as a diagnostic assay for metal allergy.

This study will eventually lead to the development of a new diagnostic approach for the determination of *oral allergy* with systemic symptoms.

Study design

Multi- center observational cross-sectional study.

Study burden and risks

Participants could benefit from the additional advice they receive about their allergy. They could gain more information about their allergy. Also, if possible, safe implant material alternatives can be proposed. Both methods (crevicular washes and sequential adhesive tape stripping) are very low risk procedures. Tape stripping can cause minor discomfort on removal and moderate erythema resulting from application and removal. The collection of blood by venipuncture is a routine clinical procedure and does not contain any specific risk.

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

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
* Patients suspected of having an allergic reaction to palladium or nickel in their dental restorative material and who are orally exposed to these metals by their dental devices and who are scheduled to receive a routine skin patch test at the outpatient clinic Dermato-allergology & occupational dermatology at the VU University Medical Centre for diagnosis of nickel and palladium allergy.
* Patients must be willing to undergo crevicular fluid collection, venipuncture and skin adhesive tape stripping

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
* Pregnancy or lactation
* Age under 18 or above 80
* Smoking, no more than ten cigarettes per day
* Legally incompetent adults
* Usage of systemic immunosuppressive drugs (e.g. prednison, acitretine, adalimumab, efalizumab, etanercept, methoxsaleen, cyclosporine, azathioprine, infliximab and methothrexate) and antibiotics at least 2 weeks prior to starting of the study NB: Medication that reasonably not intervenes with the study procedures (e.g. an antihistaminicum can be used during the study)
* Severe disorders within the last 6 month, e.g. cancer, acute cardiac- and circularity disorders, serious diabetics
* Participation in a study with pharmaceutical within a period of at least 4 weeks prior to this study
* Immunological disorders, e.g. HIV, infectious hepatitis,
* Alcohol and drug abuse
* Eating or drinking (except water) in the morning preceding the first appointment
* Brushing of the teeth (toothpaste) the morning preceding the first appointment

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:	Pending
Start date (anticipated):	01-05-2017
Enrollment:	50
Type:	Anticipated

Ethics review

Approved WMO

Date:	24-05-2018
Application type:	First submission
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	NL58719.029.16