Diagnostics of metal allergy associated with oral exposure

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To evaluate the agreement between the results of four diagnostic tests for metal allergy (in vivo patch tests, resp. Lymfocyte Proliferation Test (LPT), a modified LPT (MELISA®), and the Lymfocyte Cytokine Production Test (LCPT), and the clinical...

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

Summary

ID

NL-OMON30428

Source
ToetsingOnline

Brief title
Metal allergy diagnostics

Condition

- Other condition
- Allergic conditions
- Epidermal and dermal conditions

Synonym
Metal allergy

Health condition

tandheelkundige slijmvlies aandoeningen

Research involving
Human

Sponsors and support

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

Intervention

Keyword: dental alloys, lymfocyte proliferation test, metal allergy, patch testing

Outcome measures

Primary outcome

Determination of correlation coefficients between test results of four selected

tests mutually as well as in relation with the diagnostic image of metal

allergiy linked to an oral exposure to dental alloys.

Secondary outcome

not applicable

Study description

Background summary

Beside the contemporary in vivo epicutaneous patch test, recently also in vitro tests are described for the diagnosis of type IV metal allergies. Such allergies are usually the result of a skin contact, but may also be caused or aggrevated by oral exposure to metal alloys. In spite of the fact that patch testing is the only diagnostic system currently available for routine diagnostics in the Netherlands its value for the diagnostics of a type IV allergy, originating from an oral exposure to metals, is still unclear. Meanwhile there is discussion over the diagnostic value of the recently developed in vitro tests. This study has as aim to determine agreement between the results of in vivo patch tests, some specially selected in vitro tests and the diagnostic allergic symptoms that are linked with oral metal exposure obtained from examination and an anamnesis.
Three in vitro tests are selected, the Lymfocyte Proliferation Test (LPT), a modification of LPT (MELISA®) and a Lymfocyte Cytokine Production Test (LCPT).

Study objective

To evaluate the agreement between the results of four diagnostic tests for metal allergy (in vivo patch tests, resp. Lymfocyte Proliferation Test (LPT), a modified LPT (MELISA®), and the Lymfocyte Cytokine Production Test (LCPT), and the clinical diagnose with regard to a possible metal allergy linked to oral exposure.

Study design

Observational study

Study burden and risks

Participants of this study will be exposed to different amounts of burden. For the estimation of burden one has to differentiate between regular and experimental diagnostics. In that view the volunteers will have a larger burden than the patients involved in this study.

Diagnostic protocol of ACTA Department of Oral Diagnostics.
1. Anamnesis.
2. Intra-oral examination, comparable to a dental half year check-up.
3. Metal biopsy of metal based restorations to reveal the oral metal exposure of the patients/participant.
4. Panorama X-ray photograph, effective dose 6-11 *Sv (RIVM).
5. Communication of findings with the patient
6. Reporting to referral dentist/physician
Total time needed for this part is approximately 90 min.

Diagnostic protocol VUmc Department of Dermato-Allergology
1. Anamnesis.
2. Body examination
3. Epicutane patch testing
4. reading of test results after 48, 72 and 144 hours.
5. Communication of findings with the patient
6. Reporting to referral dentist/physician
Total time needed for this part is approximately 90 min.

Venapunction to collect 130 ml blood for the in vitro tests.

Adverse and serious adverse events
Only the venapunction and the patch testing may produce some mild adverse events.

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

Patients (>18 year) where the anamnesis gives rise to a suspicion of a metal allergy based on an oral exposure and where intra-oral inspection showed one of the following symptoms:
1) not plaque related mucosa deviation (e.g. gingivitis, periodontitis),
2) Lichenoid reaction,
3) Lingua geographica,
4) Local erosion,
5) Edema,
6) Erythema.

Exclusion criteria

Patients/volunteers where the anamnesis showed malignancies and/or systemic diseases, or other disorders that hinder the execution of in vivo or in vitro allergy testing. ;Patients/volunteers who are pregnant.;The use of drugs that interferes with in vivo and/or in vitro allergic diagnostic tests.;Patients not willing to undergo the general diagnostic examination as normally offered by the department of Dermato-Allergy (VUmc) or the department of Oral Diagnostics (ACTA).;Patients of the negative control group were not positive patch tested before and should not have a history of eczema.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2007
Enrollment:	90
Type:	Anticipated

Ethics review

Approved WMO

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	NL15650.029.06