Local and systemic antibody responses for maintaining gingival health

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Ancillary infectious topics
Study type	Observational invasive

Summary

ID

NL-OMON41332

Source
ToetsingOnline

Brief title
Antibodies for periodontal health

Condition

- Ancillary infectious topics

Synonym
gum inflammation, periodontitis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Antibodies, Immune response, Periodontitis, Plasma cells

Outcome measures

Primary outcome

From each patient, the relative frequencies of B- and T-cell subsets will be determined, both in tissue and blood. These parameters will be compared between patients and controls. Additionally, immunohistochemical analysis of paraffin embedded biopsies will be performed to assess overall morphology and cell types present. Finally, antibodies will be cloned from single sorted plasma cells, and these will be tested for their (auto-) reactivity. This will all be related to the bacterial composition in periodontitis.

Secondary outcome

nvt

Study description

Background summary

Periodontitis is a chronic inflammation of the gingival tissue leading to destruction of tooth support in the bone. Most people (90%) are relatively well-protected against the pathologic conversion from mild, reversible gingival inflammation (gingivitis) into destructive periodontitis. However, 10% of the people do develop periodontitis, for reasons unknown currently.

In the periodontitis lesion, a large leukocytic infiltrate can be found with high frequencies of plasma cells. The plasma cells have as main goal the production of antibodies (immunoglobulins). We hypothesize that in healthy individuals, IgA responses control dental plaque and biofilm formation, whereas in periodontitis abnormal IgG responses induce chronic inflammation and may also be associated with auto-immunity. Therefore, we wish to study whether local immunoglobulin responses contribute to chronic tissue destruction in periodontitis. We will investigate the control of bacteria by local and

systemic antibody production and how this is disturbed in periodontitis.

Study objective

In this project, we aim to study how local and systemic antibody by distinct B- and T-cell populations control periodontal health, in particular control the conversion of gingivitis into destructive periodontitis. Which types of B cell responses are required to control bacteria in the gingival crevice? How are these responses deregulated in patients with periodontitis?
By doing this, we hope to gain more insight in the mechanisms involved in the development of periodontitis, which might be usefull for treating periodontitis in the future.

Study design

In patients with diagnosed periodontitis or gingivitis and in healty controls, we want to study different immune cells both in tissue (locally) and in blood (systemically). With new flowcytometric and molecular techniques we want to determine for example different B- and T-cell subsets in the different groups, and clone antibodies from single sorted plasma cells and test their reactivity. The study will be cross-sectional, observational with 1x collection of blood and a microbial sample of the tooth plaque, and collection of gingival tissue (that is removed during regular treatment).

Study burden and risks

When the patient agrees to enter the research, this will be planned with a scheduled treatment. At this point, the patient will sign the informed written consent, after which 2 samples of 9ml blood will be taken and a microbial sample of the toothplaque. The total burden will thus be one venapuncture and a microbial swab (non-invasive). There are no additional health risks,only a small chance for a minor bruise due to the venapuncture, because there is no intervention.

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

* >18 and < 60 years of age
* DPSI-score between 0 and 3- for healthy controls
* No bone loss visible on radiograph for healthy controls
* Bleeding on probing for periodontitis patients
* Periodontitis patients diagnosed with periodontitis according to definition by Tonetti & Claffey (2005, Journal of Clinical Periodontology) : proximal attachment loss of * 3 mm in * 2 non-adjacent teeth
* Otherwise healthy
* Informed written consent

Exclusion criteria

* <18 and >60 years of age
* Used antibiotics in the last 3 months
* People receiving immunosuppressive therapy or taking other immunomodulating agents
* Having received periodontal treatment <2 years ago or in periodontal maintenance

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:	Recruitment stopped
Start date (anticipated):	09-12-2013
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	11-07-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-11-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-07-2015
Application type:	Amendment
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	NL43467.029.13