

# The influence of apical periodontitis on the concentration of inflammatory mediators in peripheral blood plasma and the metagenomic profiling of endodontic infections.

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The plasma concentrations of inflammatory mediators of AP subjects are similar to those of non-AP controls and elimination of the endodontic infection does not result in changes of the systemic inflammation. Finally ) to investigate the microbiome...

<b>Ethische beoordeling</b>	Positief advies
<b>Status</b>	Werving gestopt
<b>Type aandoening</b>	-
<b>Onderzoekstype</b>	Observationeel onderzoek, zonder invasieve metingen

## Samenvatting

### ID

NL-OMON23636

### Bron

NTR

### Verkorte titel

AP, health & metagenome

### Aandoening

apical periodontitis, parodontitis apicalis  
oral inflammation, ontsteking in de mond  
root canal infection, wortelkanaalinfectie  
endodontic, endodontisch  
health, gezondheid  
systemic health, algehele gezondheid  
low-grade inflammation, lage-graad ontsteking

## Ondersteuning

**Primaire sponsor:** Academic Centre Dentistry Amsterdam (ACTA), Amsterdam, The Netherlands

**Overige ondersteuning:** initiator

## Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

Changes in concentration of mediators of inflammation compared non-AP controls (i) and to baseline measurements (ii).<br>

Determination of the magnitude of the microbial infection.<br>

Determination of composition and function profile of infected AP teeth.

## Toelichting onderzoek

### Achtergrond van het onderzoek

Rationale: It is generally accepted that good oral health contributes to well-being. It is unknown however how much influence oral disease has on general health or vice versa. Even healthy persons have low quantities of inflammatory mediators in the systemic circulation and oral disease may add to these amounts thus rendering healthy persons a little less healthy. Also, oral infections are poly-microbial. To date, there is no information about which bacterial species trigger a great inflammatory response and which species do not.

Root-tip inflammation and its resolution is independent of patient compliance. Therefore, the treatment of root-tip inflammation offers a good challenge model which will allow us to study causal effects of oral health/oral disease on general health.

Objectives: First objectives: To evaluate whether in subjects with one tooth with apical periodontitis, elimination of the infection by tooth extraction will result in changes in the presence of inflammatory mediators in peripheral blood plasma. To characterise the composition and metagenome of the microbiome of root-canal infected teeth.

Second objective: To identify biomarkers of apical periodontitis.

Study design: Prospective cohort study

Study population: Healthy human volunteers, 18 – 80 yrs old, with one tooth with a non painful root tip inflammation (asymptomatic apical periodontitis). This group receives the

treatment tooth extraction. Healthy human volunteers 18-80-yrs old without apical periodontitis will be included as the healthy control group.

Main study parameters/endpoints: Evaluation of the concentration of blood plasma proteins at different time points before and after the tooth extraction and assessment of root canal infection metagenome.

## **Doel van het onderzoek**

The plasma concentrations of inflammatory mediators of AP subjects are similar to those of non-AP controls and elimination of the endodontic infection does not result in changes of the systemic inflammation. Finally ) to investigate the microbiome of root canal infections.

## **Onderzoeksopzet**

6 and 3 weeks before tooth extraction

at tooth extraction

1, 6 and 13 weeks after tooth extraction

## **Onderzoeksproduct en/of interventie**

This is a prospective cohort study. Each subject will be followed for approximately 20 weeks.

Subjects with one tooth with apical periodontitis to be treated with tooth extraction will be included. Six peripheral blood samples will be collected in a timespan from 6 weeks before to 13 weeks after tooth extraction. Controls will include healthy subjects without AP.

The plasma concentrations of 22 inflammatory mediators will be determined. Following tooth extraction, the tooth will be collected for microbial analysis.

The timeline of the individual mediators of inflammation will be evaluated. We will also look for clusters and patterns in their presence.

## **Contactpersonen**

### **Publiek**

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## Wetenschappelijk

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Inclusion criteria AP group

In order to be eligible to participate in this study, a subject must meet all of the following criteria.

- The subject is 18 - 80 years old.
- After intra-oral examination, AP has been confirmed with an intra-oral radiograph and appears on the radiograph as a radiolucent area around one or more root tips of the affected tooth. AP is diagnosed when in the periapical region, the periodontal ligament is at least twice as wide as in the mid-root regions. A root canal treatment has a poor prognosis or the patient would rather have the affected tooth extracted. The AP tooth is non-symptomatic.
- No other teeth have AP. To confirm this, front teeth are clinically examined. Discoloured teeth or teeth with restorations that do not respond to cold testing or that are tender to percussion or palpation will also be examined with an intra-oral radiograph. In the (pre)molar region, recent bite-wing radiographs are used to screen for deep restorations or dental caries. When there are doubts about the vitality of restored or decayed (pre)molars an additional radiograph is taken.
- The subject has completed the medical history questionnaire.
- The subject wants to participate and donate six blood samples at six different time points and the subject wants to donate the extracted tooth. The subject has signed the IC letter.

- The subject will not undergo dental hygienist' treatments during the study.

#### Inclusion criteria control group

- The subject is 18 - 80 years old.
- The subject has not had endodontic treatment in the past or previously root-canal treated teeth show no signs or symptoms of AP.
- The subject has completed the medical history questionnaire and is classified as healthy.
- The subject wants to participate and donate six blood samples at six different time points and the subject wants to donate the extracted tooth. The subject has signed the IC letter.
- The subject will not undergo dental hygienist' treatments during the study.

### **Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)**

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- smoking
- pregnancy or lactation
- diabetes mellitus type I
- chronic inflammatory diseases like m. Crohn
- use of antibiotics 1 month prior with an indication other than AP of the aimed tooth.
- use of corticosteroids or NSAIDs
- chemotherapy or previous head/neck irradiation
- any surgery 6 months prior
- any existing extra-oral swelling
- malaise, colds or influenza one week before or at the start of the study
- prosthesis carriers with stomatitis

- absence of periapical radiolucency in the presence of tenderness to percussion.
- absence of periapical radiolucency in the absence of sensitivity
- previous surgery on tooth considered
- vertical root fracture of tooth considered
- localised periodontitis affecting tooth considered with absence of periodontal disease at other sites

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- pregnancy or lactation
- diabetes mellitus type I
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- use of antibiotics 1 month prior
- use of corticosteroids or NSAIDs
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## Onderzoeksopzet

### Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel

Toewijzing:	Niet-gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

## Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	18-01-2017
Aantal proefpersonen:	60
Type:	Werkelijke startdatum

## Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

**Wordt de data na het onderzoek gedeeld:** Nog niet bepaald

## Ethische beoordeling

Positief advies	
Datum:	17-01-2017
Soort:	Eerste indiening

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

### In overige registers

Register	ID
NTR-new	NL6081
NTR-old	NTR6228

**Register**

Ander register

**ID**

NL54832.029.16 : ABR

## Resultaten