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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23636

Source
NTR

Brief title
AP, health & metagenome

Health condition

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

Sponsors and support

Primary sponsor: Academic Centre Dentistry Amsterdam (ACTA), Amsterdam, The Netherlands
Source(s) of monetary or material Support: initiator

Intervention

Outcome measures

Primary outcome

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

Determination of the magnitude of the microbial infection.

Determination of composition and function profile of infected AP teeth.

Secondary outcome

Presentation of cytokine timelines of resolution of AP plus healing of extraction site.

Determination of clusters of inflammatory mediators at time points S1- S6.

Correlation of subject characteristics (symptoms of AP, DMFS and DPSI, age and sex) to mediators of inflammation or clusters thereof.

Correlation of subject characteristics (symptoms of AP, DMFS and DPSI, age and sex) to qualitative and quantitative data of microbial content of extracted teeth.

Study description

Background summary

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.

Study objective

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.

Study design

6 and 3 weeks before tooth extraction

at tooth extraction

1, 6 and 13 weeks after tooth extraction

Intervention

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.

Contacts

Public
Academisch Centrum Tandheelkunde Amsterdam, Amsterdam, Netherlands
S.V. van der Waal
Gustav Mahlerlaan 3004

Amsterdam 1081 LA
The Netherlands
0031205980880
Scientific
Academisch Centrum Tandheelkunde Amsterdam, Amsterdam, Netherlands
S.V. van der Waal
Gustav Mahlerlaan 3004

Amsterdam 1081 LA
The Netherlands
0031205980880

Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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

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

- 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

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-01-2017
Enrollment:	60
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	17-01-2017
Application type:	First submission

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
NTR-new	NL6081
NTR-old	NTR6228
Other	NL54832.029.16 : ABR

Study results