

An overview of white blood cells' functioning in patients with periodontitis

Submission date 11/07/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 11/08/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 28/08/2018	Condition category Oral Health	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Periodontitis is an inflammatory disease that occurs in the oral cavity (mouth) and affects the supportive tissues of the teeth. If the inflammation progresses, this can lead to severe bone destruction and tooth loss. In response to the accumulation of microorganisms (bacteria), white blood cells called polymorphonuclear neutrophils can enter the oral cavity from the blood stream and mix in the oral fluid. The specific role of these oral PMNs (oPMNs) in periodontitis is uncertain. The aim of this study is to compare the PMNs in the mouths of people with and without periodontitis.

Who can participate?

Patients with and without untreated periodontitis

What does the study involve?

Blood and oral rinse samples are collected from patients with untreated periodontitis and people without periodontitis to measure the amount of PMNs, their activation, cell death and the generation of oxygen free radicals.

What are the possible benefits and risks of participating?

This study gives insights into the functioning of the immune response within the mouths of people with periodontitis. No risks or symptoms are expected to occur due to participating in this study.

Where is the study run from?

Academic Centre for Dentistry Amsterdam (Netherlands)

When is the study starting and how long is it expected to run for?

October 2014 to May 2016

Who is funding the study?

University of Amsterdam (Netherlands)

Who is the main contact?
Mr Patrick Rijkschroeff

Contact information

Type(s)
Scientific

Contact name
Mr Patrick Rijkschroeff

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2012-210#B2012406

Study information

Scientific Title
Characterization of functional oral polymorphonuclear neutrophils in periodontitis patients: an observational case-control study

Study objectives
Knowledge about polymorphonuclear neutrophils (PMNs) in the oral cavity periodontitis is limited and controversies exist regarding their function and significance. The rationale of this study was to characterize the PMNs from the oral cavity of patients with untreated periodontitis and compare those to the same cells from healthy subjects without periodontitis, since most of the periodontitis research on PMNs has made use of blood as the source material. Additionally, the characteristics of the oral PMNs were compared to those of the circulatory PMNs.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Study design

Observational case-control study

Primary study design

Observational

Secondary study design

Case-control study

Study setting(s)

Hospital

Study type(s)

Screening

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Periodontitis

Interventions

Venous blood and oral rinse samples were obtained from 19 patients with untreated periodontitis and 16 control subjects without periodontitis for PMN isolation. Cell numbers were counted and apoptosis was analysed using propidium iodide labelling. Expression of cell activation markers CD11b, CD63, and CD66b was analysed using flow cytometry. Constitutive ROS generation was detected using dihydrorhodamine123. Additionally, ROS production in response to stimulation was evaluated in samples incubated with 10 μ M phorbol myristate acetate (PMA) or *Fusobacterium nucleatum*.

Intervention Type

Other

Primary outcome measure

The presence of PMNs in the oral cavity of periodontitis patients, measured using flow cytometry directly after sampling. All samples were analyzed using flow cytometry on the same day.

Secondary outcome measures

1. Cell counts, measured using a Muse cell counting device
2. Cell membrane integrity, measured with flow cytometric analysis using propidium iodide staining
3. PMN expression markers of cell activation: CD11b, CD63, CD66b and corrected for non-specific binding of isotype control antibodies
4. Presence of constitutive oxygen radicals (ROS), detected using dihydrorhodamine 123

5. Presence of ROS in response to stimulation, determined in samples incubated with phorbol myristate acetate (PMA) or *Fusobacterium nucleatum*
All outcomes measured at a single timepoint

Overall study start date

01/10/2014

Completion date

01/05/2016

Eligibility

Key inclusion criteria

1. Patients with untreated periodontitis
2. The presence of bone loss on $\geq 1/3$ of the root length on minimum 2 non-adjacent teeth on vertical bite-wing radiographs not older than 12 months
3. Aged 18 and over

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

15

Key exclusion criteria

1. A history of pathologic conditions that are known to systemically affect PMN functionality (such as hematological disorders, diabetes mellitus, antibiotics use within the last 6 months, recent history of illness or fever, allergies, alcoholism and pregnancy)
2. Less than 20 teeth
3. Removable partial dentures
4. Night guards
5. Orthodontic banding
6. (Peri) oral piercings
7. Apparent oral lesions

Date of first enrolment

20/10/2014

Date of final enrolment

01/04/2016

Locations

Countries of recruitment

Netherlands

Study participating centre

Academic Centre for Dentistry Amsterdam (ACTA)

Netherlands

1081LA

Sponsor information

Organisation

University of Amsterdam

Sponsor details

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Sponsor type

University/education

Website

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ROR

<https://ror.org/04dkp9463>

Funder(s)

Funder type

University/education

Funder Name

Universiteit van Amsterdam

Alternative Name(s)

University of Amsterdam, UvA

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

Netherlands

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal.

Intention to publish date

21/09/2018

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Elena A. Nicu (e.nicu@acta.nl).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	24/08/2018		Yes	No