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

Submission date	Recruitment status	[_] Prospectively registered
11/07/2017	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
11/08/2017	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
28/08/2018	Oral Health	

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

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Additional identifiers

Protocol serial number
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)
Medical Ethics Committee of the VU University Medical Center, 29/03/2013, ref: 2012-210#B2012406

Primary study design
Observational

Study design
Observational case-control study

Study type(s)
Screening

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 μM phorbol myristate acetate (PMA) or Fusobacterium nucleatum.

Intervention Type
Other

Primary outcome(s)
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.

Key secondary outcome(s)
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

Completion date
01/05/2016

Eligibility

Key inclusion criteria
1. Patients with untreated periodontitis
2. The presence of bone loss on ≥ 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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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

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

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