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The presence of non-functional white blood cells in the mouth of edentulous subjects wearing full dentures

Submission date	Recruitment status	[_] Prospectively registered
05/09/2016	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
14/09/2016	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
14/09/2016	Oral Health	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Neutrophils are the most common type of white blood cell found in the body. They enter the mouth mostly through the small open space of the gums, surrounding the teeth. These are also known as gingival crevices. Little is known about these oral neutrophils functional potential (what they can do) and their possible contribution in the maintenance of oral health. This study aims to investigate the presence and functional capabilities of oral neutrophils in people with no teeth (edentulous) since these individuals lack the presence of the gingival crevices found in people that still have their teeth.

What does the study involve?
This study looks at neutrophils taken from people without teeth but with a healthy mouth (orally healthy) with orally healthy people with teeth (dentate). Rinse and blood samples are taken from each person and analysed for functional activity (that is, ti see what functions the neutrophils have in the mouth) on the same day. All participants are informed about the purpose of the study, are given written information and are asked for their written consent prior to the start of the study.

What are the possible benefits and risks of participating?
This observational study gives new insights in the functioning of the immune response within the mouth of people without teeth. No risks or symptoms are to be 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?
May 2014 to January 2016

Who is funding the study?
University of Amsterdam (Netherlands)

Who is the main contact?
Dr Elena Nicu

Contact information

Type(s)
Scientific

Contact name
Dr Elena Nicu

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2012-210#B2012406

Study information

Scientific Title
Impaired polymorphonuclear neutrophils in the oral cavity of edentulous subjects

Study objectives
Edentulous subjects present with less functional polymorphonuclear neutrophils compared to dentate subjects.

Ethics approval required
Old ethics approval format

Ethics approval(s)
2012-210#B2012406

Study design
Observational case-control study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
School

Study type(s)
Screening

Participant information sheet

Health condition(s) or problem(s) studied
Edentulous subjects wearing full dentures for a minimum period of 1 year.

Interventions
Volunteers were recruited at the Academic Centre for Dentistry Amsterdam (ACTA) in the Netherlands. Subjects were either patients at the dental clinics or non-professional personnel. All subjects were screened for their periodontal condition and additionally dental radiographs were taken in order to confirm the absence of alveolar bone loss. Edentulous subjects were included if they have been wearing a full denture for a minimum period of 1 year.

All subjects were informed about the purpose of the study, received written information and had given written consent prior to the start of this study. Each subject was asked to donate one blood sample and 4x oral rinse samples. Samples were donated on the same day. Venous blood samples were drawn from the antecubital fossa into one 9 ml sodium heparin blood collection tube. Oral rinse samples were taken before any other intra-oral procedures were carried out in order to avoid contamination. The edentulous subjects were asked to remove their dentures before the supervised sample collection. All subjects were instructed not to gargle nor clear their throat during the sampling procedure. Four serial rinses of the oral cavity were obtained with 10 ml of sterile sodium chloride solution (0.9%) for 30 seconds, each with 4.5 min intermission. The rinse samples were pooled into one collection tube.

Neutrophil counts were determined in blood and from oral rinses. Additionally cell functionality was determined using flow cytometry (cell membrane integrity, cell activation status and reactive oxygen species).

Intervention Type
Biological/Vaccine

Primary outcome measure
The presence of functionally impaired neutrophils in the oral cavity of edentulous subjects, measured using flow cytometry directly after sampling. All samples were analyzed using flow cytometry on the same day.

Secondary outcome measures
1. Cell number count, using a Muse cell counting device.
2. Cell membrane integrity, analysed using propidium iodide staining.
3. Neutrophil expression of cell activation markers CD11b, CD63 and CD66b and corrected for non-specific binding of isotype control antibodies.
4. Presence of constitutive reactive oxygen species (ROS) production, detected using dihydrorhodamine 123.

5. Presence of ROS production in response to stimulation, determined in samples incubated with forbid myristate acetate (PMA) or Fusobacterium nucleatum

Overall study start date
01/05/2014

Completion date
01/01/2016

Eligibility

Key inclusion criteria
edentulous for a minimum period of 1 year wearing a full denture OR dentate subjects with a minimum of 20 teeth.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
20

Key exclusion criteria
conditions that are known to systemically affect the neutrophil functionality (such as Diabetes, hematological disorders, recent illness, allergies). Furthermore, antbiotics use, pregnancy, removal partial dentures, night guards, orthodontic banding, oral piercings, oral lesions were excluded.

Date of first enrolment
01/09/2014

Date of final enrolment
01/09/2015

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Centre for Dentistry Amsterdam (ACTA)
Gustav Mahlerlaan 3004
Amsterdam

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1081 LA

Sponsor information

Organisation
Academic Centre for Dentistry Amsterdam (ACTA)

Sponsor details
Gustav Mahlerlaan 3004
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Sponsor type
University/education

ROR
https://ror.org/04x5wnb75

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

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request