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Lipid-A project

Submission date	Recruitment status	[_] Prospectively registered
08/01/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
08/01/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
23/01/2019	Oral Health	

Plain English summary of protocol

Background and study aims
Periodontitis is a chronic inflammatory disease of the tissues supporting the teeth and one of the main causes of tooth loss. It is caused by bacteria present in a shallow crevice between the gums and the teeth which triggers the host inflammatory response. This exacerbated host inflammatory response is responsible for tissue damage and the loss of the bone that supports teeth. Despite being a very common oral disease, diagnostic procedure and treatment option for periodontitis have not changed significantly for more than a century. It is usually diagnosed too late, once bone less has already occurred, and treated, not very successfully, by mechanical removal of subgingival deposites. Therefore, there is a great need for new diagnostic approaches and treatment options for this widespread disease. Bacterial species that are responsible for development of periodontal diseases are able to produce a very potent substance, lipopolysaccharide (LPS), that triggers the host inflammatory response. If this type of bacterial antigens are detected in the mouth before the development or in early stages of the disease, a successful preventive regimen could be employed and harmful consequences avoided. The aim of this study is to see if there are any differences in the chemical composition of lipopolysaccharides isolated from subgingival dental plaque, saliva from patients with gum diseases and patients with healthy gums.

Who can participate?
Adults with or without chronic periodontitis

What does the study involve?
Saliva and subgingival deposit samples are collected from both patients with periodontitis and healthy volunteers treated at the Peninsula School of Dentistry clinics in Plymouth and Truro. LPS is extracted from these samples and its chemical composition (with a focus on Lipid-A, its most potent part) examined in the research laboratories of the Plymouth University. The chemical composition of LPS is compared between healthy participants and patients with periodontitis as well as between samples from the same periodontitis patient taken before and after routine periodontal treatment.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
The Peninsula School of Dentistry clinics in Plymouth and Truro (UK)

When is the study starting and how long is it expected to run for?
August 2014 to June 2015

Who is funding the study?
GSK and Oral and Dental Research Trust (UK)

Who is the main contact?
Dr Svetislav Zaric

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
18081

Study information

Scientific Title
Subgingival plaque lipid-A profile as a bacterially-derived biomarker for chronic periodontitis

Study objectives
Are there differences in the chemical composition of lipopolysaccharides isolated from subgingival dental plaque and saliva from patients with gum diseases and patients with healthy gums?

Ethics approval required
Old ethics approval format

Ethics approval(s)

NRES Committee South West - Cornwall and Plymouth, 03/03/2014, ref:14/SW/0020

Study design
Non-randomised study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Oral & Dental; Subtopic: Oral & Dental Public Health; Disease: All Oral & Dental

Interventions
1. Full mouth periodontal therapy
2. Full mouth periodontal debridement

Intervention Type
Procedure/Surgery

Primary outcome(s)
Change in subginigval lipid-A profile; Timepoint(s): 3 months after completion of periodontal therapy

Key secondary outcome(s))
N/A

Completion date
30/06/2015

Eligibility

Key inclusion criteria
1. Healthy (PD <4 mm, no evidence of attachment and bone loss, and <10% of sites with BOP)
2. Chronic periodontitis (presence of 1/3 bone loss or more and presence of 6 mm pocket or more, with evidence of attachment loss at 2 or more teeth per quadrant and evidence of generalized bleeding)

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Systemic chronic diseases
2. Acute medical interventions or diseases 4 weeks before baseline
3. Pregnancy
4. Antibiotics 6 months before intake and or repeated use of NSAID's medications 4 weeks before intake

Date of first enrolment
20/08/2014

Date of final enrolment
30/06/2015

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Plymouth
Peninsula Dental School
Plymouth University
Portland Square C406
Plymouth
United Kingdom
PL4 8AA

Sponsor information

Organisation
Peninsula Dental Social Enterprise CIC

ROR
https://ror.org/04dtfyh05

Funder(s)

Funder type
Government

Funder Name
GSK and Oral and Dental Research Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available. The participant level data is confidential and is stored in the patients' record system SoelHealth.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2019	22/01/2019	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes