

# Lipid-A project

<b>Submission date</b> 08/01/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 08/01/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 23/01/2019	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data

## 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 loss has already occurred, and treated, not very successfully, by mechanical removal of subgingival deposits. 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

Dr Svetislav Zaric

### ORCID ID

<http://orcid.org/0000-0003-4127-0253>

### Contact details

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

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

**Secondary study design**

Non randomised study

**Study setting(s)**

Other

**Study type(s)**

Treatment

**Participant information sheet**

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

**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 measure**

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

**Secondary outcome measures**

N/A

**Overall study start date**

20/08/2014

**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

### Age group

Adult

### Sex

Both

### Target number of participants

Planned Sample Size: 60; UK Sample Size: 60; Description: 30 patients with chronic periodontitis and 30 individuals with healthy periodontium

### 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

England

United Kingdom

### 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

### Sponsor details

Peninsula Dental School  
Plymouth University  
Portland Square C406  
Plymouth  
England  
United Kingdom  
PL4 8AA

### Sponsor type

Hospital/treatment centre

### ROR

<https://ror.org/04dtfyh05>

## Funder(s)

### Funder type

Government

### Funder Name

GSK and Oral and Dental Research Trust (UK)

## Results and Publications

### Publication and dissemination plan

Results of the study will be reported and disseminated by conference presentations and peer reviewed scientific journal publications by the end of 2017.

### Intention to publish date

31/12/2017

### 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?
<a href="#">Results article</a>	results	01/09/2019	22/01/2019	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No