

# Changes in the gum condition of smokers who substitute the use of e-cigarettes for their regular smoking habits

<b>Submission date</b> 03/02/2016	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 05/02/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 01/07/2020	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Smokers have worse gum disease and are more likely to lose teeth than non-smokers. When smokers stop smoking, the condition of their gums changes and become similar to a non-smoker. E-cigarettes contain nicotine and are gaining popularity, but we do not know what e-cigarettes do to the gums. We plan to study the gum condition of smokers with mild gum disease who stop smoking cigarettes for 2 weeks and use e-cigarettes instead. Gum disease can change the amount of certain chemicals in the blood, saliva and the fluid that collects in the crevice between the gum and the tooth. The amount of those chemicals changes when people stop smoking, but we do not know what happens to them when e-cigarettes are used.

### Who can participate?

Smokers with mild gum disease who do not intend to quit smoking but would be prepared to substitute e-cigarettes instead of smoking for 2 weeks

### What does the study involve?

We measure the gum condition of a group of smokers who do not intend to quit smoking. We also take blood from a vein in the arm, collect saliva and the fluid that collects in the crevice between the gum and the tooth. The smokers stop smoking cigarettes for 2 weeks and we provide e-cigarettes for them to use instead. After 2 weeks we measure the gum condition again and collect samples of blood, saliva and gum fluid again.

### What are the possible benefits and risks of participating?

There are no particular benefits for people who take part except to try out e-cigarettes at no cost to themselves. There are also no particular risks except minor discomfort during the gum examination and during collection of blood.

### Where is the study run from?

King's College London (UK)

When is the study starting and how long is it expected to run for?  
November 2014 to July 2016

Who is funding the study?  
King's College London (UK)

Who is the main contact?  
Dr Veronica Booth

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Veronica Booth

**Contact details**  
Floor 21  
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## Additional identifiers

**EudraCT/CTIS number**  
Nil known

**IRAS number**

**ClinicalTrials.gov number**  
Nil known

**Secondary identifying numbers**  
161226

## Study information

**Scientific Title**  
Changes in the gingival condition and inflammatory mediators of smokers who substitute the use of e-cigarettes for their regular smoking habits.

**Study objectives**  
There will be no change in the gingival condition of smokers after 2 weeks of substituting e-cigarette use for normal smoking habits.

Secondary objectives of the project are to compare the concentrations of inflammatory markers in the saliva, gingival crevicular fluid and the plasma after cigarette smoking and e-cigarette use.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

NRES Committee London - London Bridge, 23/01/2015, ref: 14/LO/2092

**Study design**

Single-centre longitudinal pilot study

**Primary study design**

Observational

**Secondary study design**

Longitudinal study

**Study setting(s)**

Hospital

**Study type(s)**

Prevention

**Participant information sheet**

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

**Health condition(s) or problem(s) studied**

Gingival inflammation

**Interventions**

The study involves smokers with mild periodontal (gum) disease who do not intend to quit smoking but would be prepared to substitute e-cigarettes instead of smoking for 2 weeks. The aim would be to compare gum inflammation in the smokers when smoking cigarettes with their condition after using e-cigarettes for 2 weeks. Subjects would provide samples of saliva and the gingival crevicular fluid that collects in the crevice between the gums & and teeth (GCF) and also venous blood. Examining the biochemical markers of inflammation within blood, saliva & GCF would help to determine whether the substitution of e-cigarettes modifies the subjects' inflammatory response in mild periodontal disease.

**Intervention Type**

Other

**Primary outcome measure**

The number of gingival sites bleeding after probing, measured at baseline and 2 weeks

**Secondary outcome measures**

1. The volume of gingival crevicular fluid, measured at baseline and 2 weeks
2. The concentration of biomarkers in plasma and gingival crevicular fluid, measured at baseline and 2 weeks

**Overall study start date**

06/11/2014

**Completion date**

31/07/2016

## Eligibility

**Key inclusion criteria**

1. Subjects must have at least 24 natural teeth, excluding third molars
2. Subjects must have smoked at least 5 cigarettes/day for at least 5 years
3. They will be systemically healthy individuals who have mild periodontal disease with no pocket depth over 5 mm at any site

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

20

**Total final enrolment**

20

**Key exclusion criteria**

1. Subjects with any systemic condition known to exacerbate or modulate periodontal disease e. g., diabetes
2. Have taken antibiotics in the previous 3 months
3. Take any anti-inflammatory drugs regularly
4. Take other medication likely to affect the periodontal tissue e.g., calcium channel blocking drugs
5. Pregnant or nursing mothers
6. Patients with nut allergies will be excluded as the nicotine-containing fluid may contain traces of nuts

**Date of first enrolment**

27/04/2015

**Date of final enrolment**

04/12/2015

# Locations

## Countries of recruitment

England

United Kingdom

## Study participating centre

### King's College London

Guy's & St Thomas's Hospital

Floor 21

Tower Wing

London

United Kingdom

SE1 9RT

# Sponsor information

## Organisation

King's College London (UK)

## Sponsor details

Room 1.1

Hodgkin Building

Guy's Campus

London Bridge

London

United Kingdom

SE1 1UL

## Sponsor type

University/education

## ROR

<https://ror.org/0220mzb33>

# Funder(s)

## Funder type

University/education

## Funder Name

Kings College London

**Alternative Name(s)**

King's College, King's College London UK, KCL, King's

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Universities (academic only)

**Location**

United Kingdom

## Results and Publications

**Publication and dissemination plan**

M.Clin Dent. project to be submitted by 31/07/2016

**Intention to publish date**

31/07/2016

**Individual participant data (IPD) sharing plan****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	01/12/2016	01/07/2020	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No