ISRCTN17182047 https://doi.org/10.1186/ISRCTN17182047

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

Submission date
03/02/2016

Recruitment status
No longer recruiting

Registration date
05/02/2016

Overall study status
Completed

Last Edited
01/07/2020

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
Guy's Tower Wing
Great Maze Pond
London Bridge
London
United Kingdom
SE1 9RT

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Prevention

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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

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)

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

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?
Results article	results	01/12/2016	01/07/2020	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes