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Impact of smoking on gums

Submission date	Recruitment status	[_] Prospectively registered
15/01/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/02/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
22/01/2019	Oral Health	

Plain English summary of protocol

Background and study aims
Cigarette smoking is one of the major risk factors for gum disease. The aim in this study is to assess the impact of cigarette smoking on healthy and diseased gum tissue.

Who can participate?
Adult smokers and non-smokers

What does the study involve?
Samples will be obtained of the fluid secreted where the gums meet the teeth.

What are the possible benefits and risks of participating?
There are no known benefits to participants taking part in this study. There are no known risks to participants taking part in this study.

Where is the study run from?
Ondokuz Mayıs University (Turkey)

When is the study starting and how long is it expected to run for?
From September 2012 to March 2014

Who is funding the study?
Ondokuz Mayıs University (Turkey)

Who is the main contact?
Associate Professor Muge Lutfioglu

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Ref No: B.30.2.ANK.0.21.63.00/824-02/9-8

Study information

Scientific Title
Interleukin 8 and lipoxin a4 levels in the gingival crevicular fluid of smokers and non-smokers with different periodontal diseases: a cross-sectional study

Study objectives
Investigate the effect of cigarette smoking on gingival crevicular fuid levels of interleukin 8 and lipoxin A4, cytokines that affect the polymorphonuclear functions in inflammatory response, in healthy individuals and those with periodontal disease because:
1. Cigarette smoking is one of the major risk factors for periodontal disease and has effects on the pathogenesis of the periodontal disease.
2. Smoking alters the host's response, including vascular function, neutrophil/monocyte activities, adhesion molecule expression, antibody production and cytokine and inflammatory mediator release.
3. Loss of proinflammatory mediators is the turn off signal for inflammation, ending subsequent responses passively
4. Resolution of inflammation and the return to homoeostasis is an active and highly regulated biochemical process that is thought to be programmed at the tissue level.
5. Failure to the remove the noxious products of smoking will have negative effects on cellular functions of the ımmune system and inflammatory cells might cause chronic and pathological lesions in healthy and diseased periodontal tissues.
6. Specialised immunoresolvents comprise endogeneous molecules including resolvins, lipoxins, protectins and maresins, which actively drive the termination of the inflammation.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Local ethics committee of the Dental School of Ankara University, 19/07/2011, reference number B.30.2.ANK.0.21.63.00/824-02/9-8

Study design
Cross-sectional observational study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
A study population of smokers and nonsmokers was selected regarding the criteria: (i) to be ≥ 18 years of age and having ≥ 16 teeth, (ii) not to have previous periodontal therapy in the last 6 months, and (iii) not to have any systemic problems and regular/current (at least 6 weeks prior to data collection) chemotherapeutic regimens. Smoking status was determined as ≥ 5 years of duration and as ≥ 15 per day of consumption in all smokers, whereas non-smoking status included individuals who never smoked before.

Health condition(s) or problem(s) studied
Periodontial disease is a leucocyte-mediated inflammatory disease characterised by inflammation of the supporting tissues of the teeth induced by micro-organisms that stimulate the host immune and inflammatory responses.

Interventions
Gingival crevicular fluid samples will be obtained from the orifice of the gingival pocket, using commercially available periopaper strips for the assessment of:
1. Plaque index
2. Gingival index
3. Probing depth
4. Clinical attachment level
5. Bleeding on probing

Intervention Type
Other

Primary outcome measure
1. Silness and Loe plaque index
2. Loe and Silness gingival index
3. Probing pocket depth
4. Clinical attachment level
5. Bleeding on probing

Clinical measurements will be performed on six sites per tooth (mesio-buccal, mid-buccal, disto-buccal, mesio-lingual, mid-lingua and, disto-lingual) using a Williams periodontal probe calibrated in millimetres on the patient's first visit to have periodontal treatment.

Secondary outcome measures
N/A

Overall study start date
01/09/2012

Completion date
30/03/2014

Eligibility

Key inclusion criteria
1. Smokers (≥ 5 years of duration and ≥ 15 cigarettes per day)
2. Non-smokers (never smoked)
3. Age ≥ 18 years old
4. ≥ 16 teeth

Participant type(s)
Other

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
15 smokers and 15 non-smoker participants

Key exclusion criteria
1. History of cancer
2. History of rheumatoid arthritis
3. History of diabetes mellitus
4. History of cardiovascular diseases
5. Compromised immune system
6. Pregnancy
7. Menopause
8. Lactating
9. Ongoing drug therapy that may affect the clinical features of periodontitis
10. Systemic antimicrobials during the 6 weeks preceding the baseline examination
11. Any dental treatment during the past 6 months

Date of first enrolment
01/09/2012

Date of final enrolment
30/03/2014

Locations

Countries of recruitment
Türkiye

Study participating centre
Ondokuz Mayıs University
Dental Faculty
Samsun
Türkiye
55139

Sponsor information

Organisation
Ondokuz Mayıs University

Sponsor details
Dental Faculty
Samsun
Türkiye
55139

Sponsor type
University/education

ROR
https://ror.org/028k5qw24

Funder(s)

Funder type
University/education

Funder Name
Ondokuz Mayıs University (Turkey)

Results and Publications

Publication and dissemination plan
Planning to send the manuscript for publication in March 2015

Intention to publish date
31/03/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2016	22/01/2019	Yes	No