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Periodontitis and obesity

Submission date	**Recruitment status**	[_] Prospectively registered
17/05/2018	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/06/2018	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
04/03/2022	Oral Health	

Plain English summary of protocol

Background and study aims
The body is made up of different elements: water, protein, mineral and fat. The combination of these is referred to as body composition. The proportion of these elements varies from individual to individual. Body composition is categorised using BMI (calculated from height and weight). The WHO has categorised BMI according to categories associated with various elements of health and disease (for example, BMI normal 20 - 24.9, BMI overweight 25 - 29.9, BMI obese ≥30). Elements of body composition have been shown to affect the body's immune response resulting in increased susceptibility to infections. For example, fat cells are responsible for the production and release of several pro-inflammatory secretions. These can often result in a state of low-grade systemic inflammation and altered insulin sensitivity. Chronic periodontitis (gum disease) is an inflammatory disease influenced by many factors. Research has shown that differences from one person to another in the way the body responds to plaque bacteria is a key factor affecting gum disease susceptibility and healing response. The aim of this study is to investigate the effect of elements of body composition on healing response following non-surgical periodontal therapy.

Who can participate?
Patients aged 35 and over with BMI between 20-24.9 (WHO Normal) or BMI ≥30 (WHO Obese) and severe periodontal disease

What does the study involve?
There are 8 planned study visits. At Visit 1 the following are recorded: health history, medications or supplements taken normally, height, weight, waist circumference, body fat assessment, blood pressure, pulse, and body temperature. Samples are taken including sample of blood (fasting), saliva sample, sample of gingival fluid from around selected teeth, and plaque samples from selected teeth. A clinical examination of the oral tissues including those supporting the teeth is performed (measurements to assess the level and health of the gum tissue). Participants are asked to complete a diet diary at home for 3 days (2 weekdays and 1 weekend day). At Visit 2 the treatment plan is presented and methods to effectively clean the teeth at home are discussed. This is an important part in order to achieve successful and long-lasting results of any gum therapy. The diet diary is collected at this visit. At Visit 3 blood pressure, pulse, and body temperature are measured. The treatment clinician performs full mouth non-surgical periodontal debridement (removal of calcified deposits above and below the gum margin). Extraction of teeth with hopeless prognosis is carried out (as agreed upon at Visit

2). At Visit 4 a health history update, blood pressure, pulse and body temperature are taken as per visit 1. Blood (fasting), saliva and plaque samples are also taken. At Visit 5 a health history update, blood pressure, pulse, and body temperature are taken as per visit 1. Blood (fasting), saliva and plaque samples are also taken. At Visit 6 oral hygiene routine is checked and tooth polishing is performed (health history update is taken). At Visit 7 the following are recorded: health history update, medications or supplements taken normally, weight, waist circumference, body fat assessment, blood pressure, pulse, and body temperature. Samples are taken including sample of blood (fasting), saliva sample, sample of gingival fluid from around selected teeth, and plaque samples from selected teeth. A clinical examination of the oral tissues including those supporting the teeth is performed (measurements to assess the level and health of the gum tissue). Tooth polishing is performed. A diet diary is requested as per Visit 1. Visit 8 takes place 6 months after treatment is performed and is the same as Visit 7. In addition the diet diary is collected as per Visit 2.

What are the possible benefits and risks of participating?
Periodontal treatment in both groups will reduce the infection in the mouth and improve the longevity of the teeth. Periodontal probing, periodontal treatment and dental anaesthesia injections, if necessary, may involve some discomfort. Blood collection may also cause some discomfort. If signs of disease worsening over the study period are detected, participants are treated with the standard required therapy. If extensive treatment is required they may be withdrawn from the study.

Where is the study run from?
UCL Eastman Dental Institute (UK)

When is the study starting and how long is it expected to run for?
April 2009 to January 2013

Who is funding the study?
Joint UCLH/UCL Biomedical Research Unit (UK)

Who is the main contact?
Dr Jeanie Suvan

Contact information

Type(s)
Scientific

Contact name
Dr Jean Suvan

Contact details
256 Gray's Inn Road
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Perio-08-38

Study information

Scientific Title
Effects of body composition on clinical, immunological, and microbiological outcomes following non-surgical periodontal therapy in patients with chronic periodontitis: a cohort study

Acronym
BoCoP

Study objectives
Null hypothesis: There is no association between obesity and the response to non-surgical periodontal therapy in adults with chronic periodontitis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London - Surrey Borders Research Ethics Committee, 23/11/2009, REC ref: 09/H0806/43

Study design
Single-centre cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Obesity and chronic periodontitis

Interventions

Both groups (BMI obese and BMI normal) received standard non-surgical periodontal therapy consisting of oral hygiene instructions and full mouth debridement within 24 hours, with 6 months follow-up.

Intervention Type
Procedure/Surgery

Primary outcome measure
Periodontal probing pocket depth at 2 and 6 months following completion of non-surgical intensive periodontal therapy

Secondary outcome measures
1. Percentage of periodontal pockets >4 mm at 2 and 6 months
2. Full mouth bleeding on probing percentage at 2 and 6 months

Overall study start date
02/04/2009

Completion date
17/01/2013

Eligibility

Key inclusion criteria
1. Individuals at least 35 years of age and in good general health
2. Have BMI between 20-24.9 (WHO Normal) or BMI ≥30 (WHO Obese)
3. Participants must have a minimum of 15 natural teeth
4. Participants must have severe periodontal disease defined as >30% sites with PPD ≥5 attachment loss (1998 AAP classification)
5. Participants must voluntarily agree to sign the consent form

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
114

Total final enrolment
115

Key exclusion criteria
1. BMI between 25-29.9 (WHO overweight)
2. Current smokers or former smokers who have smoked within the previous 5 years
3. History of diabetes

4. Uncontrolled or currently undergoing treatment for serious systemic medical conditions including hepatic disease, renal disease, transmittable diseases, cancer, or HIV
5. On chronic treatment (defined as 2 weeks or more) of antibiotic, anti-inflammatory or anticoagulant therapy during the month preceding the baseline exam
6. History of alcohol or drug abuse
7. Self reported pregnancy or lactation (this criterion is due to oral tissue changes related to pregnancy and nursing which can affect interpretation of study results)
8. Other severe acute or chronic medical or psychiatric condition or laboratory abnormality that may increase the risk associated with study participation or may interfere with the interpretation of study results and, in the judgment of the investigator, would make the subject inappropriate for entry into this study
9. Participation in any other dental study concurrently

Date of first enrolment
02/12/2009

Date of final enrolment
25/06/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
UCL Eastman Dental Institute
Unit of Periodontology
256 Gray's Inn Road
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Sponsor information

Organisation
Joint UCLH/UCL Biomedical Research Unit

Sponsor details
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Sponsor type
Research organisation

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Research organisation

Funder Name
Joint UCLH/UCL Biomedical Research Unit

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal within the next 8-12 months.

Intention to publish date
04/06/2019

Individual participant data (IPD) sharing plan
The dataset is not available as future analysis are still planned. The data is held as part of UCL Eastman Dental Institute.

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		20/02/2020	04/03/2022	Yes	No