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Periodontitis Vascular Dysfunction

Submission date 25/02/2014	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 25/02/2014	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 18/04/2017	**Condition category** Digestive System	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Moderate to severe periodontitis (PD) has been associated with a 20% increased risk of heart disease. Gum Disease may directly affect arteries wall structure, impair their dilatation capacity (ability to increase blood flow) and predispose to atherosclerosis (build up of fat). The nature of this association, however, has not yet been established. Treatment of periodontitis may also cause a transient state of systemic inflammation (swelling) with increase of concentrations of specific blood proteins (called acute phase proteins). This inflammatory state represents the body response to the local therapy and could affect blood vessels in the body. This study aims to understand better the possible impact if any, of periodontal disease (gum disease) on cardiovascular risk and general health.

Who can participate?
Adults over the age of 18 who have moderate to severe PD.

What does the study involve?
Participants either receive an intensive periodontal therapy or a control (fake therapy). Participants are asked to attend 15 visits to the study centre over 24 months. Participants are assessed for changes in acute phase proteins using non-invasive high resolution ultrasound scans of the arm and change in the thickness of the carotid arteries assessed by ultrasounds. Participants also may have a cycle of ischemia of their arm and its consequences on blood vessels.

What are the possible benefits and risks of participating?
Participants may benefit from improvement in their periodontal condition. There are no notable risks with participating.

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

When is the study starting and how long is it expected to run for?
April 2013 to December 2019

Who is funding the study?
University College London (UK)

Who is the main contact?
Dr Francesco D'Aiuto

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
14996

Study information

Scientific Title
Intensive treatment for periodontal disease: A model of and therapy for inflammatory vascular dysfunction

Study objectives
The possible aetiological role of infections on the development and progression of cardiovascular diseases has attracted greater attention over the last twenty years. Individuals with periodontitis present with a modest but statistically significant increased risk of vascular events compared to controls.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London Queen Square Research Ethics Committee, 19/11/2012, ref: 06/Q0512/107

Study design

Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Topic: Oral and Gastrointestinal; Subtopic: Oral and Gastrointestinal (all Subtopics); Disease: Oral & Dental

Interventions
Current interventions as of 18/04/2017: Participants are randomly allocated to one of two groups. Participatns are asked to atten 15 visits, including a screening visit, baseline visits, and visits for their treatment.

Intensive periodontal treatment (IPT) group receive an intensive treatment consisting of mechanical debridement of the diseased dentition in a single session (4-6 hrs).

Control periodontal therapy (CPT): Participants receive an control therapy consisting of oral hygiene instructions, supragingival mechanical instrumentation and polishing.

Participants may also be randomised into have remote ischemic preconditioning or a matched placebo.

Previous interventions:
IPT and CPT, Individuals included into the intervention study will be randomized to two different periodontal therapy regimens: CPT or IPT. Patients in the IPT group will receive an intensive treatment consisting of mechanical debridement of the diseased dentition in a single session (4-6 hrs). Local anaesthesia will be used as necessary.
Control group patients (CPT) will receive oral hygiene instructions, supragingival mechanical instrumentation and polishing.

Intervention Type
Other

Phase
Phase II/III

Primary outcome measure

Current primary outcome measure as of 18/04/2017:
Common carotid intima media thickness (c-IMT) is measured using an ultrasound at baseline, 12 and 24 months.

Previous primary outcome measures:
C-IMT; Timepoint(s): 12 Months, 24 Months

Secondary outcome measures
Current secondary outcome measures:
1. Brachial artery flow-mediated dilatation (FMD) is measured using a blood pressure cuff at baseline, 24 hours and 1 week after periodontal treatment.
2. Pulse-wave velocity is assessed at baseline, two, six, 12, 18 and 24 months after peridontal treatment
3. Blood inflammatory markers are measured using blood tests at baseline, two, six, 12, 18 and 24 months after peridontal treatment
4. Oxidative stressis assessed at baseline, two, six, 12, 18 and 24 months after peridontal treatment
5. Masticatory function is assessed at two time-points.

Previous secondary outcome meaures:
1. Biomarkers; Timepoint(s): Every 6 months for 24 months
2. Clinical Periodontal Measures; Timepoint(s): Every 12 months
3. FMD; Timepoint(s): Every 6 months up to 24 months
4. PVW; Timepoint(s): Every 6 months up to 24 months

Overall study start date
01/04/2013

Completion date
01/12/2019

Eligibility

Key inclusion criteria
1. Subject must be > 18 years
2. Subject must have moderate to severe PD (at least 30 periodontal pockets >4mm with Bleeding on Probing)
3. Subject must have voluntarily signed the informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 284; UK Sample Size: 284

Key exclusion criteria
1. Female subject is pregnant or lactating or of childbearing and not using acceptable methods of birth control
2. Subject is on chronic treatment (i.e., two weeks or more) with specific medications known to affect periodontal status (phenytoin or cyclosporine) within one month of baseline visit
3. Subject knowingly has HIV or Hepatitis
4. Subject has limited mental capacity or language skills such that simple instructions cannot be followed or information regarding adverse events cannot be provided
5. Subjects on chronic antibiotic therapy or who require antibiotic coverage for periodontal procedures
6. Subjects had a course of periodontal therapy in the preceding 6 month

Date of first enrolment
01/04/2013

Date of final enrolment
01/12/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Eastman Dental Institute
256 Gray's Inn Road
London
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WC1X 8LD

Sponsor information

Organisation
University College London (UK)

Sponsor details
Academic Unit Respiratory Medicine
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Sponsor type
University/education

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Industry

Funder Name
Johnson & Johnson Consumer Services (EAME) Ltd

Funder Name
NIHR University College London Hospitals Biomedical Research Centre; Grant Codes: F189

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
31/12/2020

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date