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Periodontitis and type 2 diabetes mellitus

Submission date	Recruitment status	[_] Prospectively registered
18/06/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/06/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/02/2019	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Background and study aims
Type 2 diabetes and gum disease (periodontitis) are common diseases and often found in the same patients. There is strong evidence to suggest that diabetes predisposes patients to gum disease and vice versa. The mechanism linking both diseases could be increased body inflammation affecting both sugar control and gum health. Ongoing gum disease could make it harder for people with diabetes to control their sugar levels. The aim of this study is therefore to assess whether treating gum disease improves sugar levels (metabolic control) in patients with type 2 diabetes.

Who can participate?
Patients aged 18 and over with type 2 diabetes and moderate to severe gum disease

What does the study involve?
Participants undergo an oral examination, blood sample and some blood vessels scans at their first visit and at 2, 6 and 12 months after the start of their gum/dental treatment. After the first study visit, participants are randomly allocated into two groups: one group receive an intensive course of gum/dental therapy and the other group receive scaling and polishing. All participants are monitored every 3 months up to 1 year from the start of the gum treatment.

What are the possible benefits and risks of participating?
Participants benefit from an update on their oral and gum health. They receive treatment from a professional dedicated team of specialists/dentists/hygienists to look after their gum condition within and beyond the duration of the study. The study does not involve any drug treatment but involves frequent blood samples and blood vessel scanning (ultrasound scans) (every 2-3 months).

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?
July 2007 to January 2015

Who is funding the study?
1. Diabetes UK
2. NIHR Biomedical Research Centre UCL/ULCH (UK)

Who is the main contact?
1. Prof. Francesco D’Aiuto
f.daiuto@ucl.ac.uk
2. Dr Jean Suvan
j.suvan@ucl.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Francesco D'Aiuto

ORCID ID
http://orcid.org/0000-0001-8654-935X

Contact details
Study Principal Investigator
UCL Eastman Dental Institute
256 Gray's Inn Road
London
United Kingdom
WC1X 8LD
-
f.daiuto@ucl.ac.uk

Type(s)
Scientific

Contact name
Dr Jean Suvan

Contact details
UCL Eastman Dental Institute
Periodontology Unit
256 Grays Inn Road
London
United Kingdom
WC1X 8LD
-
f.daiuto@ucl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
5280

Study information

Scientific Title
Treatment of periodontitis and metabolic control in patients with type 2 diabetes mellitus: a single-centre randomised interventional trial

Acronym
DRN211

Study objectives
Current hypothesis as of 26/09/2017:
Untreated periodontitis impacts on patients' oral health and overall quality of life. Periodontitis could worsen metabolic control, vascular function in patients with type 2 diabetes via an increased systemic inflammatory burden. The trialists therefore hypothesized that effective treatment of periodontitis, which results in reduction of local and systemic inflammation, would improve glycaemic control, as well as vascular and renal function and quality of life in patients with type 2 diabetes.

Previous hypothesis:
This study aims at assessing the potential benefit of successful periodontitis treatment on glucose control in people with type 2 diabetes. The secondary aims include changes in vascular function, wound healing and inflammation and quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Joint UCL/UCLH Committees on the Ethics of Human Research, 27/11/2007, ref: 07/H0714/97

Study design
Parallel-arm single (examiner) blinded randomized controlled single-centre trial

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 in the interventions section to request a patient information sheet.

Health condition(s) or problem(s) studied
Topic: Diabetes Research Network, Oral and Gastrointestinal; Subtopic: Type 2, Oral and Gastrointestinal (all Subtopics); Disease: Cardiovascular disease, Diabetic Control, Other, Oral & Dental

Interventions
Participants will be randomly assigned to either usual periodontal care (supragingival scaling and polishing) or to an intensive periodontal treatment (test group). Blood samples will be collected at almost every visit to assess glucose control between study groups. Samples will also be collected to assess the changes in wound healing and blood vessel health before and after gum therapy in both groups. A subgroup of 30 participants will also undergo more detailed analysis of gingival wound healing processes after periodontal therapy. Study follow-up is at 12 months.

Study entry: single randomisation only

Contact details for Patient Information Material:
Eastman Clinical Investigation Centre
256 Gray's Inn Road
London, WC1X 8LD
United Kingdom
Tel: +44 (0)20 7915 2334
Fax: +44 (0)20 7915 1213

Intervention Type
Other

Phase
Phase III

Primary outcome measure
Change in HbA1c between test and control group after 12 months of completion of therapy

Secondary outcome measures
Current secondary outcome measures as of 26/09/2017:
1. HbA1c difference at 6 months
2. Glucose, insulin, creatinine and flow-mediated dilatation at 6 and 12 months
3. Adverse events at any study visits
4. Periodontal clinical parameters, lipid fractions, inflammatory and endothelial cell surface markers at 2, 6 and 12 months
5. eGFR and patient reported outcomes at 12 months
6. Changes in dental plaque composition at 2, 6 and 12 months visits
7. Laser Doppler flowmetry of the skin at all study visits, a subgroup of 30 patients will also have laser Doppler measures of their gums following intensive gum therapy
8. Intima-media thickness and endothelium pulse amplitude tonometry changes at 12 months (subgroup of 115 patients)

Previous secondary outcome measures:
1. To assess the impact of extensive periodontal therapy on:
1.1. Markers of gingival wound healing
1.2. Assessment of endothelial function
1.3. Subclinical atherosclerosis
1.4. Systemic inflammation
1.5. Proteinuria
1.6. Microbiological differences
In individuals with type 2 diabetes compared to control
2. To assess changes in quality of life, both related to diabetes and oral health, after extensive periodontal therapy compared to control

Overall study start date
01/07/2007

Completion date
01/01/2015

Eligibility

Key inclusion criteria
1. Subject aged over 18 years, either sex
2. Subject diagnosed with type 2 diabetes mellitus
3. Subject consenting to the study
4. Subject with signs of active moderate to severe periodontitis (at least 20 periodontal pockets, probing pocket depth [PPD] greater than 4 mm and bleeding on probing)
5. Minimum of 15 teeth present

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned sample size: 280; UK sample size: 280

Key exclusion criteria
1. Pregnancy/lactation
2. Subjects on chronic treatment with phenytoin or cyclosporin
3. Subjects with known human immunodeficiency virus (HIV) or hepatitis (B, C) or uncontrolled systemic diseases (cardiovascular diseases including hypertension, liver, pulmonary diseases, end stage renal failure) and/or neoplasm
4. Subjects who require antibiotic coverage for periodontal procedures

Date of first enrolment
01/10/2007

Date of final enrolment
31/10/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
UCL Eastman Dental Institute
London
United Kingdom
WC1X 8LD

Sponsor information

Organisation
UCL Eastman Dental Institute and Hospital, University College London (UK)

Sponsor details
256 Gray's Inn Road
London
England
United Kingdom
WC1X 8LD

Sponsor type
Hospital/treatment centre

Website
www.ucl.ac.uk/eastman

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type

Charity

Funder Name
Diabetes UK (UK) (ref: 08/0003594 and 08/0003741)

Alternative Name(s)
DIABETES UK LIMITED, British Diabetic Association

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Funder Name
NIHR Biomedical Research Centre UCL/ULCH

Results and Publications

Publication and dissemination plan
1. A main manuscript with the primary and secondary results will be published in a peer-review journal (under review)
2. UCL Team will be presenting the main results at dental and medical scientific meetings
3. UCL Media Relations would make every effort to publicise any appropriate information relevant to the study results to the international press
4. Electronic copies of any research papers arising from this work will be made freely available at the UCL repository of journal articles
5. Dissemination of the relevant findings to the general public, press, companies will be pursued using the UCL Public Engagement in Science website

Intention to publish date
01/12/2017

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Results article	results	01/12/2018	Yes	No