

Periodontitis and type 2 diabetes mellitus

Submission date 18/06/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results <input type="checkbox"/> Individual participant data
Registration date 18/06/2010	Overall study status Completed	
Last Edited 18/02/2019	Condition category 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
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Contact information

Type(s)

Scientific

Contact name

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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?
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[Results article](#)

results

01/12/2018

Yes

No