

Eliminating periodontal infection in patients with type 2 diabetes

Submission date 21/05/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 21/05/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 13/12/2019	Condition category Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
4678

Study information

Scientific Title

Eliminating periodontal infection in patients with type 2 diabetes: a single centre non-randomised observational diagnosis and treatment study

Acronym

DRN149 (DDP)

Study objectives

Periodontal disease is emerging as a recognised complication of diabetes, and epidemiological data support that patients with type 2 diabetes mellitus (T2DM) have increased prevalence and severity of periodontitis. Furthermore, recent preliminary data suggest that diabetes control in patients with periodontitis may be improved following successful periodontal treatment.

In this study, we will perform a full periodontal examination and glycaemic control will be measured (HbA1c) in 160 T2DM individuals aged 30 - 55 years. For those patients who are diagnosed as having periodontal disease (estimated n = 40), we will treat their disease using established periodontal treatment methods to eliminate the periodontal infection. The patients will be monitored for 12 months following treatment and changes in HbA1c at months 3, 6 and 12 following treatment will be measured. We will also measure cytokine and adipokine levels in the gingival crevicular fluid (GCF), saliva and in serum, including interleukin-6 (IL-6) and tumour necrotising factor-alpha (TNF-alpha) in all patients at screening, and before and after treatment in those patients with periodontal disease to understand better the pathogenic processes common to both diseases. 40 controls (non-diabetic patients who have periodontal disease) will also be recruited.

This research will provide fundamental information on associations between periodontal inflammation and glycaemic control and will evaluate the effect of periodontal therapy on glycaemic control in T2DM patients with periodontal disease.

Ethics approval required

Old ethics approval format

Ethics approval(s)

MREC approved on the 28th February 2006 (ref: 06/Q0904/8)

Study design

Single centre non-randomised observational diagnosis and treatment study

Primary study design

Observational

Secondary study design

Non randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Topic: Diabetes Research Network, Oral and Gastrointestinal, Primary Care Research Network for England; Subtopic: Type 2, Oral and Gastrointestinal (all Subtopics); Disease: Other, Oral & Dental

Interventions

Conventional periodontal therapy in patients with periodontal disease.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Serum HbA1c, lipid profile, high sensitivity C-reactive protein (hsCRP)
2. Inflammatory cytokines (IL-1b, TNF-a, IL-6, INF-y)

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/05/2006

Completion date

30/03/2010

Eligibility

Key inclusion criteria

Not provided at time of registration

Participant type(s)

Patient

Age group

Adult

Sex

Not Specified

Target number of participants

Planned sample size: 160; UK sample size: 160

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/05/2006

Date of final enrolment

30/03/2010

Locations

Countries of recruitment

England

United Kingdom

Study participating centre**School of Dental Sciences**

Newcastle upon Tyne

United Kingdom

NE2 4BW

Sponsor information

Organisation

Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

Sponsor details

Queen Victoria Road

Newcastle Upon Tyne

England

United Kingdom

NE1 4LP

Sponsor type

Hospital/treatment centre

Website

<http://www.newcastle-hospitals.org.uk/>

ROR

<https://ror.org/05p40t847>

Funder(s)

Funder type

Charity

Funder Name

Dunhill Medical Trust (UK)

Alternative Name(s)

The Dunhill Medical Trust, DMT

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration