

# Eliminating periodontal infection in patients with type 2 diabetes

<b>Submission date</b> 21/05/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 21/05/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 13/12/2019	<b>Condition category</b> 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