

# Treatment of gum disease in patients with diabetes mellitus

<b>Submission date</b> 04/09/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 23/09/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 10/01/2012	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Francesco D'Aiuto

**Contact details**  
Periodontology Unit  
Division of Clinical Research  
UCL Eastman Dental Institute  
256 Grays Inn Road  
London  
United Kingdom  
WC1X 8LD

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
PE\_DiaPD\_001

# Study information

## Scientific Title

Treatment of periodontitis and metabolic control of patients with diabetes mellitus: a controlled clinical trial

## Acronym

TeDiPe

## Study objectives

To ascertain the impact of periodontal therapy on basic measures of glycaemic control in a population of type 1 and 2 diabetes suffering from mild to moderate periodontitis.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

University of Medicine of Perugia Academic Board approved on the 26th November 2002 (ref: 1211)

## Study design

Non-randomised controlled clinical trial

## Primary study design

Interventional

## Secondary study design

Non randomised controlled trial

## Study setting(s)

Other

## 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

Diabetes mellitus (DM), periodontitis (PD)

## Interventions

Intervention group:

1. Oral hygiene instructions and general explanations about PD
2. Intensive periodontal therapy, consisting of:
  - 2.1. Extraction of compromised teeth
  - 2.2. Scaling and root planning of all diseased sites within 24 hours using both ultrasonic and hand instruments
3. Four re-call appointments (at 1, 2, 4 and 8 months respectively)

Control group individuals received a course of standard scaling and polishing.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

Changes in HbA1c after 8 months of therapy between cases and controls.

**Secondary outcome measures**

Changes in periodontal parameters after therapy between cases and controls, recorded at baseline, 4 and 8 months after periodontal therapy.

**Overall study start date**

01/09/2003

**Completion date**

01/09/2005

**Eligibility****Key inclusion criteria**

1. Aged 35 to 70 years, either sex
2. Type 1 and 2 diabetes at the department of Endocrinology of Perugia Hospital
3. Presenting with mild to moderate periodontitis (defined as at least six sites in the mouth exhibited probing depths equal or greater than 4 mm; in each patient, bone loss was confirmed by an radiographic assessment)

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

Cases = 44, controls = 49 (total = 93)

**Key exclusion criteria**

1. Presenting with signs of acute infections
2. Uncontrolled diabetes complications
3. Infectious diseases such as hepatitis or human immunodeficiency virus (HIV) infection
4. Patients requiring antibiotic prophylaxis before dental procedures
5. Patients who received a course of systemic antibiotic or periodontal therapy within the preceding 3 months

**Date of first enrolment**

01/09/2003

**Date of final enrolment**

01/09/2005

## **Locations**

**Countries of recruitment**

England

Italy

United Kingdom

**Study participating centre****Periodontology Unit**

London

United Kingdom

WC1X 8LD

## **Sponsor information**

**Organisation**

University of Perugia (Università degli Studi di Perugia) (Italy)

**Sponsor details**

c/o Dr Calabrese Antonio

Dipartimento di Medicina Interna e Scienze Endocrine e Metaboliche

Perugia

Italy

06100

**Sponsor type**

University/education

**Website**

<http://www.unipg.it/>

**ROR**

<https://ror.org/00x27da85>

## **Funder(s)**

**Funder type**

Hospital/treatment centre

**Funder Name**

University of Perugia (Università degli Studi di Perugia) (Italy) - Department of Internal Medicine and Endocrinology

## 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

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/11/2011		Yes	No