

# 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**  
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## Additional identifiers

**Protocol serial number**  
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

**Study type(s)**

Treatment

**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(s)**

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

**Key secondary outcome(s)**

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

**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

### Healthy volunteers allowed

No

### Age group

Adult

### Sex

All

### 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

United Kingdom

England

Italy

### Study participating centre

**Periodontology Unit**  
London  
United Kingdom  
WC1X 8LD

## Sponsor information

### Organisation

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

### 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

### 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
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes