

Treatment of gum disease in patients with diabetes mellitus

Submission date 04/09/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 23/09/2009	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 10/01/2012	Condition category 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

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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)

Primary study design

Interventional

Study design

Non-randomised controlled clinical trial

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?
Results article	results	01/11/2011		Yes	No