ISRCTN00559156 https://doi.org/10.1186/ISRCTN00559156

Treatment of gum disease in patients with diabetes mellitus

Submission date	Recruitment status	[_] Prospectively registered
04/09/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/09/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/01/2012	Nutritional, Metabolic, Endocrine	

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

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