

Periodontal treatment for improving glycaemic control in diabetic patients

Submission date 12/03/2009	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol ☐ Statistical analysis plan ☒ Results ☐ Individual participant data
Registration date 30/04/2009	Overall study status Completed	
Last Edited 30/10/2019	Condition category Nutritional, Metabolic, Endocrine	

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
PHRC 0803108

Study information

Scientific Title

Periodontal treatment for improving glycaemic control in diabetic patients: a randomised controlled trial

Acronym

DIAPERIO

Study objectives

Periodontal treatment could lead to an improvement in HbA1c levels in metabolically unbalanced diabetic patients suffering from periodontitis.

We will therefore test the null hypothesis that periodontal treatment does not reduce the HbA1c level in metabolically unbalanced diabetic patients suffering from periodontitis.

Secondary objectives of this study are to assess among metabolically unbalanced diabetic patients suffering from periodontitis:

1. Whether periodontal treatment could lead to an improvement in fructosamin levels
2. Whether periodontal treatment could lead to an improvement in life quality
3. Whether periodontal treatment is safe and effective

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Committee for Protection of Research Subjects (Comité de Protection des Personnes [CPP]), Sud-Ouest Outre-Mer I, approved on 23/02/2009
2. Sanitary Safety in Health Products Agency (Agence française de sécurité sanitaire des produits de santé [AFSSAPS]), approved on 12/02/2009 (ref: 2008-A01467-48)
3. Advisory Committee for Data Processing in Health Research (Comité consultatif sur le traitement de l'information en matière de recherche dans le domaine de la santé [CCTIRS]), approved on 15/01/2009

Primary study design

Interventional

Study design

Randomised single-blind two-centre controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Diabetes mellitus, periodontal disease

Interventions

Periodontal treatment will include non-surgical scaling and root planing, systemic antibiotherapy, oral health instructions and antiseptic prescription. It will be performed within 10 days after inclusion for the treatment group, and after 100 days after inclusion for the control group.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Difference between 3-month and baseline HbA1c levels.

Key secondary outcome(s)

Difference between 3-month and baseline values of the following:

1. Fructosamin levels
2. Quality of life (SF-36® Health Survey)
3. Adverse clinical outcome event
4. Periodontal Inflamed Surface Area (PISA)

Completion date

31/12/2010

Eligibility

Key inclusion criteria

1. Male or female, aged ≥ 18 year old
2. Diabetes mellitus (type I or II), diagnosed since at least one year
3. HbA1c levels comprised between 7.0 and 9.5%
4. No change in diabetic medication 3 months before inclusion
5. Periodontal disease (at least one site on at least 4 teeth with Probing Pocket Depth ≥ 4 mm AND Clinical Attachment Loss ≥ 3 mm)
6. At least 6 remaining teeth
7. Subject able to understand and willing to provide written informed consent in French
8. Subject affiliated to the security system

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Total final enrolment

91

Key exclusion criteria

1. Receiving antibiotherapy or chronic steroid therapy
2. Presence of significant renal disease, as indicated by creatinine clearance less than 60 ml/min
3. Have another medical condition likely to cause hospitalisation within 4 months
4. Presence of serious or unstable infectious disease, hepatic disease, phenylketonuria
5. Subject at risk of endocarditis
6. Pacemaker
7. Antithrombotic treatment
8. History of allergy to amoxicillin and clindamycin
9. Pregnant, lactating, or plans to become pregnant during the study
10. Participation in another study with an investigational compound

Date of first enrolment

01/05/2009

Date of final enrolment

31/12/2010

Locations

Countries of recruitment

France

Study participating centre

CHU de Toulouse

Toulouse

France

31400

Sponsor information

Organisation

University Hospital of Toulouse (CHU de Toulouse) (France)

ROR

<https://ror.org/017h5q109>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

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	02/08/2009		Yes	No
Results article	results	01/10/2018	30/10/2019	Yes	No