ISRCTN15334496 https://doi.org/10.1186/ISRCTN15334496

Periodontal treatment for improving glycaemic control in diabetic patients

Submission date	Recruitment status
12/03/2009	No longer recruiting
Registration date	**Overall study status**
30/04/2009	Completed
Last Edited	**Condition category**
30/10/2019	Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
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

Study design
Randomised single-blind two-centre controlled trial

Primary study design
Interventional

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, phenylcetonuria
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

University Hospital of Toulouse (CHU Toulouse) (France) - Hospital Clinical Research Programme (Programme Hospitalier de Recherche Clinique [PHRC], inter-régional 0803108)

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