

# Periodontal treatment for improving glycaemic control in diabetic patients

<b>Submission date</b> 12/03/2009	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/04/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 30/10/2019	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

**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 measure**

Difference between 3-month and baseline HbA1c levels.

**Secondary outcome measures**

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)

**Overall study start date**

01/05/2009

**Completion date**

31/12/2010

**Eligibility****Key inclusion criteria**

1. Male or female, aged  $\geq 18$  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  $\geq 4$  mm AND Clinical Attachment Loss  $\geq 3$  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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

150

**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)

**Sponsor details**

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Hôtel Dieu

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**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.chu-toulouse.fr/>

**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****Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****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	02/08/2009		Yes	No
<a href="#">Results article</a>	results	01/10/2018	30/10/2019	Yes	No