# Periodontal treatment for improving glycaemic control in diabetic patients

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

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Dr Jean-Noel Vergnes

#### Contact details

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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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes