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# Impact of treatment of chronic periodontitis on the serum levels of prohepcidin in patients with chronic kidney disease

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| **Submission date**<br>07/11/2010 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>18/11/2010 | **Overall study status**<br>Completed | |
| **Last Edited**<br>03/01/2012 | **Condition category**<br>Oral Health | |

**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**
# 942.248.2006/report # 327/2006

## Study information

**Scientific Title**
Impact of treatment of chronic periodontitis on the serum levels of prohepcidin in patients with chronic kidney disease: Interventional controlled clinical assay

## Acronym
UFJF

## Study objectives
We hypothesized that part of the chronic inflammatory response seen in chronic kidney disease (CKD) patients stems from chronic periodontitis (CP), which, through the increase in the expression of inflammatory markers such as interleukin-6 (IL-6), stimulates hepcidin synthesis.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Ethics Committee in Research on Human Beings from UFJF approved on the 6th of December 2006 (ref: 942.248.2006 / report: 327/2006)

## Primary study design
Interventional

## Study design
Interventional controlled clinical assay

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Chronic periodontitis (CP); chronic kidney disease (CKD); Prohepcidin

## Interventions
Patients with CP were divided into two groups: CKD patients and controls
Both groups received instructions on oral hygiene techniques, including the manual techniques of tooth and interproximal brushing, and on how to use dental floss and perform supragingival prophylaxis. The nonsurgical periodontal therapy (PT) consisted of radicular scraping and subgingival curettage, using standard instrumentation with Gracey curettes and ultrasound devices performed in 1 hour sessions over an average period of 4 weeks. Local anesthesia was used when necessary.

Upon concluding the periodontal treatment, participants were followed up after 15, 30, 60, and 90 days. At each return visit, instructions on oral hygiene and supragingival phrophylaxis were provided.

Blood samples were collected for biochemical analysis at baseline and 3 months after PT. Venous blood after 12 hours fasting was collected in vacuum tubes between 7:00am and 9: 00am. Plasma samples with EDTA/heparin and serum samples were immediately placed in ice, aliquoted within 1 hour and stored at -80C until use.

Results:
The efficacy of PT was proven by the statistically significant decrease in the levels of inflammatory markers and the improvement of clinical parameters of CP observed 3 months after completion of the PT. Prohepcidin, IL-6 and us-PCR levels diminished significantly after PT

in both groups. In the control group, besides the decrease in the inflammatory markers, a significant increase could also be observed in the levels of haemoglobin and ferritin associated with PT.

### Intervention Type
Other

### Phase
Not Applicable

### Primary outcome(s)
Inflammatory markers, assessed at baseline and 3 months post-PT
1. C-reactive protein (us-CRP)
2. Interleukin-6 (IL-6)
3. Prohepcidin

### Key secondary outcome(s)
Biochemical analyses from blood sample in EDTA, at baseline and 3 months post-PT
1. Complete haemogram (automated Coulter STKS)
2. Serum iron (ferrozine)
3. Ferritin (electrochemiluminescence)
4. Transferrine saturation index (labtest ferrozine)

### Completion date
10/08/2010

## Eligibility

### Key inclusion criteria
1. Patients with CP, allocated to one of two groups depending on CKD status
1.1. CKD group:
1.1.1. Patients with CKD at stages 3 to 5 and undergoing conservative treatment
1.1.2. Recruited from the PREVENRIM, a CKD prevention clinic at the Interdisciplinary Nucleus of Studies, Research and Treatment in Nephrology (NIEPEN) of the Universidade Federal de Juiz de Fora (UFJF)
1.2. Control patients:
1.2.1. Patients with no systemic disease from the Periodontology Clinic of the School of Dentistry at UFJF
2. Over 18 years of age, either sex
2. Minimum of 20 natural teeth and without periapical lesions
3. Have received no periodontal, antimicrobial, or anti-inflammatory treatment within the last 6 months
4. Have not used steroids or immunosuppressant drugs within the last 6 months

### Participant type(s)
Patient

### Healthy volunteers allowed
No

**Age group**
Adult

**Lower age limit**
18 Years

**Sex**
All

**Key exclusion criteria**
1. Pregnant or breast feeding women
2. Smokers or ex-smokers who had quit smoking within the last 10 years

**Date of first enrolment**
10/08/2008

**Date of final enrolment**
10/08/2010

# Locations

**Countries of recruitment**
Brazil

**Study participating centre**
**Rua Dr Geraldo Moutinho 55**
Juiz de Fora
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# Sponsor information

**Organisation**
Federal University of Juiz de Fora (Universidade Federal de Juiz de Fora [UFJF]) (Brazil)

**ROR**
https://ror.org/04yqw9c44

# Funder(s)

**Funder type**
University/education

**Funder Name**
Federal University of Juiz de Fora (Universidade Federal de Juiz de Fora [UFJF]) (Brazil)

# 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 | 01/07/2011 | | Yes | No |