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

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

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
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)

Study design
Interventional controlled clinical assay

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 contact details below to request a patient information sheet.

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

Secondary outcome measures
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)

Overall study start date
10/08/2008

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
56

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
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Sponsor information

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

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Sponsor type
University/education

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

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?
Results article	results	01/07/2011		Yes	No