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Study to evaluate the clinical effect of chondroitin sulfate as adjunctive therapy in periodontitis disease

Submission date	Recruitment status	[ ] Prospectively registered
01/12/2014	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
22/01/2015	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
22/01/2015	Oral Health	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Periodontitis (PD) is a very common chronic gum infection that damages the soft tissue and destroys the bone supporting the teeth. It can lead to tooth loss, difficulties chewing, poor appearance of teeth and gums and it can even increase the risk of a heart attack or stroke. It is caused by the build-up of bacteria in the mouth (oral bacteria) which, over time, combines with saliva and small food particles to form a sticky film over the teeth, called plaque. The bacteria in the plaque can result in gum disease, leading to swollen, painful gums. If not treated, this gum disease will get worse and will develop into periodontitis. There is no specific pharmacological (drug) treatment for PD and treatment mainly involves good oral hygiene and removing the plaque by scaling and root planning. Here, we want to see if taking chondroitin sulphate (CS), an important chemical found in cartilage, can help treat periodontal disease in patients that also suffer from osteoarthritis (OA). We also want to and to determine salivary biomarker levels of periodontitis.

Who can participate?
PD Patients older than 40, with knee, hand or hip OA taking CS for their OA.

What does the study involve?
All patients in the study are prescribed 800 mg of oral CS once daily. Their periodontitis is assessed at the beginning of the study, and then 3, 6, 9, and 12 months later.

What are the possible benefits and risks of participating?
Possible benefits are related with anti-inflammatory effect of CS on periodontitis. Possible side effects include upset stomach, nausea, heartburn, and diarrhoea.

Where is the study run from?
The Rheumatology service from Hospital del Mar, Barcelona (Spain)

When is study starting and how long is it expected to run for?
December 2009 to September 2012

Who is funding the study?
Rheumatology service from Hospital del Mar, Barcelona (Spain)

Who is the main contact?
1. Dr. Jordi Monfort
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MON-CON-2009-01

Study information

Scientific Title
Pilot, open-label, observational, prospective study to evaluated the clinical effect of chondroitin sulfate adjunctive therapy in patients with periodontitis

Study objectives
It is hypothesized that the adjunctive treatment with chondroitin sulfate reduces the clinical signs and symptoms in periodontitis patients. This reduction will be reflected in the levels of salivary biomarkers.

Ethics approval required
Old ethics approval format

Ethics approval(s)

IMAS-Hospital del Mar, 21/07/2009, ref. (2009/3610/I

Study design
Pilot, open-label, observational, prospective study

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
GP practice

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
Periodontal disease - a chronic inflammatory process of the periodontal tissue.

Interventions
Osteoarthritic patients were prescribed 800 mg of oral CS once daily (Condrosan®, Bioiberica, S. A., Spain) for this disease, before being eligible to enter the study. Once enrolled were asked not to change their recommended oral hygiene habits or receive additional periodontal treatments throughout the study duration

Intervention Type
Supplement

Primary outcome measure
Patients were assessed at baseline 3, 6, 9, and 12 months.
1. Assessment of the periodontal pocket is calculated with CPITN in the more affected dental piece in each sextant of the oral cavity.
2. Gingival inflammation status evaluation Löe and Silness index is recorded from Ramfjord dental pieces (1.6, 2.1,2.4, 3.6, 4.1, 4.4).

In addition, for the establishment of the bone dental support status an orthopantomography (Siemens Ortophos orthopantomograph, PACS software, image scale 1:1) is carried out at baseline, month 6, and end of follow up (month 12). The loss of bone was assessed through the measurement in mm of the distance between the cemento-enamel junction and the bone margin in the 3 most affected teeth.
The pattern of alveolar bone destruction is assessed by a unique expert dentist, by quantifying the vertical defects, which reflex the slow and chronic lesions; and well as horizontal defects, more related to the teeth support and hence in the tooth loss.

Secondary outcome measures

Biomarkers of inflammation (IL-1, IL-18, TNF-alfa, and PGE2) matrix degradation (MMP-8) and bone metabolism markers (osteopontin, OPG and RANKL) are measured in the saliva collected at baseline, 3,6,9 and 12 months. The biomarkers were measured by means of custom made protein microarray except for PGE2 levels that were quantified using an enzyme-linked immunosorbent assay kit.

Overall study start date
01/12/2009

Completion date
30/09/2012

Eligibility

Key inclusion criteria
1. Patients > 40 years
2. Fulfilled the American College of Rheumatology classification criteria for clinical knee, hand or hip OA
3. Initiated CS treatment for their OA
4. Had PD of any severity grade as assessed by the Community Periodontal Index Treatment Needs (CPITN)
5. Had PD of grades II, III or IV as assessed with the Löe and Silness gingival index

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
20

Key exclusion criteria
1. Uncompensated cardiopathy;
2. Impaired renal or liver function;
3. Uncompensated asthma; severe infection
4. Human Immunodeficiency Virus
5. History of alcohol or substance abuse
6. Any currently uncompensated psychiatric disorder
7. Fibromyalgia
8. Uncompensated thyroid disease
9. Having a contraindication to CS use

Date of first enrolment
10/03/2010

Date of final enrolment
30/06/2012

Locations

Countries of recruitment
Spain

Study participating centre
Rheumatology Service, Hospital del Mar
Dr. Aiguader 88
Barcelona
08003
Spain
Barcelona
Spain
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Sponsor information

Organisation
Rheumatology Service, Hospital del Mar

Sponsor details
Passeig Marítim de la Barceloneta, 25-29
Barcelona
Spain
08003

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03a8gac78

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Rheumatology Service, Hospital del Mar (Spain)

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration