

Non-surgical periodontal therapy in rheumatoid arthritis patients

Submission date 17/09/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 24/11/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 24/11/2016	Condition category Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and aim:

Several studies suggest a two-way link between rheumatoid arthritis and periodontal (gum) disease. There have been studies that have looked into the effect of non-surgical periodontal therapy on the severity rheumatoid arthritis but the results are contradictory. The bacteria *Porphyromonas gingivalis* is thought to play an important role in periodontal disease and possibly rheumatoid arthritis. However, this has not been confirmed as there is a lack of evidence. The aim of the study was to compare the effect of non-surgical periodontal treatment on clinical symptoms and severity of inflammation in patients with moderate to severe chronic periodontitis (long term inflammatory gum disease) and rheumatoid arthritis with patients with gum disease but not suffering from rheumatoid arthritis.

Who can participate?

Adults over 30 with moderate or severe chronic periodontitis and with or without rheumatoid arthritis.

What does the study involve from a participants perspective:

All patients from all groups have a dental examination to confirm that they are suffering from chronic periodontitis. They all then receive non-surgical periodontal therapy at all teeth affected by the disease. They also have an oral hygiene assessment, are given instructions to correct brushing technique, have a professional teeth cleaning performed by a doctor, and undergo further cleaning under local anaesthesia of the roots of all affected teeth. Before treatment, at 3 and 6 months after treatments, saliva samples from the gingiva of the 4 most badly affected teeth are taken with paper points and strips. Furthermore, patients suffering of rheumatoid arthritis, undergo a thorough examination of their arthritis, again before treatment, at 3 months and 6 months, which includes the taking of blood samples for assessment.

What are the possible benefits and risks of participating?

All participants benefit from thorough dental examinations. All participants confirmed as having periodontitis, will benefit of non-surgical periodontal treatment. Patients with rheumatoid arthritis will also benefit from a of thorough of their condition. No risks are to be expected.

Where is the study run from?

Clinic for Prosthetic Dentistry, University of Medicine and Pharmacy "Iuliu Hatieganu" Cluj-Napoca

When is the study starting and how long is it expected to run for?

Janaury 2012 to August 2015

Who is funding the study?

University of Medicine and Pharmacy Cluj Napoca, Romania

Who is the main contact?

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

#580/13.04.2012

Study information

Scientific Title

Effects of non-surgical periodontal therapy on periodontal laboratory and clinical data as well as on disease activity in patients with rheumathoid arthritis

Acronym

RA-PA

Study objectives

Non-surgical periodontal treatment improves clinical periodontal, microbiological and inflammatory variables in chronic periodontitis (CP) patients with rheumatoid arthritis (RA) and without RA.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee (Comisia de etica) of the University of Medicine and Pharmacy "Iuliu Hatieganu", Cluj-Napoca, Romania, 13/04/2012, ref: #580/13.04.2012

Study design

Single-centre prospective non-randomized interventional clinical trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Chronic periodontitis

Interventions

This study is comparing the effect of non-surgical periodontal treatment on clinical and inflammatory parameters in patients with moderate to severe chronic periodontitis and rheumatoid arthritis with systemically healthy periodontitis patients.

For all patients, at baseline and again at 3 and 6 months after non-surgical periodontal treatment (scaling and root planing SRP), medical and smoking history, clinical periodontal variables (i.e. full mouth plaque score (FMPS), periodontal pocket depth (PD), clinical attachment level (CAL), bleeding on probing (BOP)) were recorded; furthermore, gingival crevicular (GCF) and subgingival plaque were sampled. For RA patients, the following rheumatological parameters were determined at the same timepoints by one specialised rheumatologist: diseases activity score 28 (DAS28), erythrocyte sedimentation rate (ESR), C reactive Protein (CRP) and rheumatoid factor (RF).

Oral hygiene instructions and professional prophylaxis sessions were performed until each patient had a FMPS $\leq 30\%$. Thereafter, non-surgical periodontal treatment (SRP) was performed within 24 hours by one experienced periodontist as follows: under local anesthesia, all pockets with PD ≥ 4 mm were scaled and root-planed to the bottom of the pocket with ultrasonic instruments (Kavo Sonicflex Scaler, Kavo Dental GmbH, Biberach, Germany) and Gracey curets (Hu Friedy, Chicago, IL, USA); treated pockets were then thoroughly rinsed with 0.2% chlorhexidine digluconate solution (Corsodyl®, GlaxoSmithKline, Brentford, London, UK) and patients were instructed to rinse twice daily for 2 minutes with a 0.2% chlorhexidine digluconate solution (Corsodyl®, GlaxoSmithKline, Brentford, London, UK) and to brush their teeth with 0.2% chlorhexidine digluconate tooth paste (Elugel®, Pierre Fabre, Paris, France) for 14 days.

Oral hygiene instructions and professional prophylaxis sessions:

Dental plaque was colored by means of a dye and the FMPS was assessed. By this dental

brushing mistakes were visible to the patients and the correct brushing technique was explained. Furthermore, use of dental floss or interdental brushes was demonstrated and explained. Finally, supragingival plaque and calculus was removed by means of a rubber cup or ultrasonic scaler.

Follow-up: at 3,6 and 12 months patients were recalled for follow-up. At every session the clinical periodontal parameters PD, FMPS, CAL, BOP were assessed, professional tooth cleaning was performed, rheumatological parameters CRP, DAS28, ESR and RF were determined. Furthermore, subgingival plaque samples were obtained by means of sterile paper strips and paper points from the 4 deepest pocket depths in the mouth for evaluation of the periodontal bacteria and inflammatory markers.

Intervention Type

Primary outcome(s)

The decrease of CRP in the patients with rheumatoid arthritis at 3 months (The CRP level, measured as counts, was determined from blood samples in the laboratory of the Clinic of Rheumatology of the University Iuliu Hatieganu Cluj-Napoca).

Key secondary outcome(s)

1. Changes (from baseline to 6 months) of CRP at 6 months
2. ESR, measured in a similar to the CRP at 3 and 6 months in the RA-CP group
3. DAS28 at 3 and 6 months in the RA-CP group (was calculated using a formula and the ESR value),
4. BOP (calculated as %)
5. FMPS (calculated as %)
6. PD (value measured clinically at teeth in mm)
7. CAL (value measured clinically at teeth in mm)
8. Number of sites PD \geq 4 mm incl. their changes (the sites with values of PD \geq 4mm were counted)
9. Qualitative and quantitative analysis of microorganisms (by means of real-time polymerase chain reaction- is a laboratory test, the are parameters reported as counts of bacteria and number of patients that presented these bacteria)
10. Inflammatory markers in sulcus fluid (these are measured by ELISA Test, a laboratory test, where also the inflammatory markers are reported as counts, and the number of patients the presented the investigated inflammatory markers) at 3 and 6 months for both patient groups

Unless otherwise stated, outcomes were measured at 3 months and 6 months.

Completion date

03/08/2015

Eligibility

Key inclusion criteria

1. Moderate or severe chronic periodontitis; >30 years of age
2. \geq 10 natural teeth present in the oral cavity
3. Full-mouth plaque scores (FMPS) \leq 30% after oral hygiene instructions
4. No other systemic diseases or medications except for RA, which are known to influence periodontal conditions/treatment outcome (e.g. Down Syndrome, HIV, Diabetes Mellitus type 1 and 2)
5. DAS28 \geq 3.2

6. No infectious or heart diseases that need prophylactic administration of antibiotics before dental treatment

7. No liver disease; no head and neck radiation therapy

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Non-surgical periodontal therapy within the previous 12 months
2. Systemic or local use of antibiotics within the previous 3 months
3. Medication with a possible influence on the periodontium (e.g., ciclosporines, phenytoines, calcium channel blockers)
4. Pregnancy or lactation

In the RA group, RA was diagnosed according to the criteria set by the American College of Rheumatology;

Date of first enrolment

01/05/2012

Date of final enrolment

16/12/2014

Locations

Countries of recruitment

Romania

Study participating centre

Clinic for Prosthetic Dentistry, University of Medicine and Pharmacy "Iuliu Hatieganu" Cluj-Napoca

Cluj-Napoca

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Sponsor information

Organisation

University of Medicine and Pharmacy Cluj-Napoca

ROR

<https://ror.org/051h0cw83>

Funder(s)**Funder type**

University/education

Funder Name

University of Medicine and Pharmacy Cluj Napoca, Romania

Funder Name

Department of Periodontology, University of Bern, Switzerland

Funder Name

SCIEX- The scientific exchange program NMS.CH (project number 12.188)

Funder Name

European Commission (FP7-HEALTH-F3-2012-306029 "TRIGGER")

Funder Name

Postdoctoral grant POSDRU Grant no. 159/1.5/S/138776 (TRANSCENT)

Results and Publications**Individual participant data (IPD) sharing plan**

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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