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Relationship between gum disease and rheumatoid arthritis in Vietnamese patients

Submission date
24/06/2020

Recruitment status
No longer recruiting

Registration date
26/06/2020

Overall study status
Completed

Last Edited
18/08/2020

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Periodontitis is a severe gum infection that can lead to tooth loss and other serious health complications. Rheumatoid arthritis is a long-term condition that causes pain, swelling and stiffness in the joints. The condition usually affects the hands, feet and wrists. Periodontitis (PD) is common in patients with rheumatoid arthritis (RA). The aim of this study is to evaluate the effects of non-surgical periodontal treatment on Vietnamese patients with active RA and periodontitis.

Who can participate?
Adult patients diagnosed with active RA and PD from previous study

What does the study involve?
Patients are divided randomly into two groups: the treatment group and the control group. Both groups are treated with conventional regimens. The control group only will have oral hygiene instruction while the treatment group receive an advanced periodontal treatment intervention, including supragingival scaling and root planning, reviewing the effect after 3 and 6 months, and treating again after each evaluation. Each patient receives an explanation about the treatment procedure for both groups from an investigator. At the end of the study, the control group receive an advanced periodontal treatment intervention. At the end of the study, the control group will receive an advanced periodontal treatment intervention.

What are the possible benefits and risks of participating?
By the end of the study, all patients receive free advanced periodontal treatment (including supragingival scaling and root planning). There are no risks of participating.

Where is the study run from?
Cho Ray Hospital (Viet Nam)

When is the study starting and how long is it expected to run for?
September 2011 to December 2014

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Nguyen Bich Van
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
12135-DHYD

Study information

Scientific Title
Effects of non-surgical periodontal treatment in Vietnamese rheumatoid arthritis patients

Study objectives
The researchers aimed to evaluate the effects of non-surgical periodontal treatment on clinical characteristics and serum indices in Vietnamese patients with active RA and periodontitis (PD).

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 02/07/2012, Ethics Committee of the University of Medicine and Pharmacy at Ho Chi Minh City (217 Hong Bang Street, W11, D5, Ho Chi Minh City, Viet Nam; +83 8558411; no email provided), ref: No.1781/DHYD-HD

Study design
Single-center interventional randomized controlled trial

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 to request a participant information sheet

Health condition(s) or problem(s) studied
Periodontal disease and rheumatoid arthritis (RA)

Interventions
Rheumatoid arthritis is diagnosed according to ACR/EULAR 2010 (American College of Rheumatology/ European League Against Rheumatism). The periodontal condition is detected by a periodontist following the criteria of Machtei, 1992. Both groups are treated with conventional regimens.

The assignment of each patient to a study group is determined by means of a randomization technique using sealed and numbered envelopes; details of the sequence were concealed from all clinicians who participated in the study. A staff member not involved in the subsequent experimentation generates a random allocation sequence, in a 1:1 ratio, for distribution of the patients to one of the two groups.

The control group only receive oral hygiene instruction while the treatment group receive an advanced periodontal treatment intervention, including supragingival scaling and root planning, reviewing effect after 3 and 6 months respectively, and retreating after each evaluation.

The study team consists of a periodontist recording periodontal indices, a rheumatologist assessing swollen and tender joints, and an assistant. Researchers treat periodontitis for RA patients, not involving in periodontal as well as the joint examination. Team members are trained by experts before the study, achieving consistency from 80% to 90.4%.

The disease activity score 28 based on CRP (DAS28-CRP), disease activity classification, rheumatoid factor (RF), erythrocyte sedimentation rate (ESR) and reactive Protein - C (CRP) are recorded and monitored at baseline, 3 and 6 months later after undergoing periodontal treatment.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Periodontal indicators (plaque index (PlI), gingival index (GI), %BOP (percentage of sites with bleeding on probing), probing pocket depth (PPD), and clinical attachment loss (CAL)) measured at six positions in all teeth at baseline, 3 and 6 months
2. Pain measured using the visual analogue score (VAS) at baseline, 3 and 6 months
3. Pain and swelling of 28 joints assessed using DAS28-CRP activity score at baseline, 3 and 6 months

Secondary outcome measures
Serum concentrations of rheumatoid factor (RF) and CRP measured with a latex particle-enhanced method at baseline, 3 and 6 months

Overall study start date
01/09/2011

Completion date
01/12/2014

Eligibility

Key inclusion criteria
1. Adult patients diagnosed with active RA and PD from previous cross-sectional descriptive study
1.1. Rheumatoid arthritis was diagnosed according to ACR/EULAR 2010
1.2. The periodontal condition was detected by a periodontist following the criteria of Machtei, 1992

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
82

Total final enrolment
82

Key exclusion criteria
1. Patients less than 30 years old
2. RAs with other polyarthritides such as polymyalgia, gout, pseudogout, spinal stiffness, Sjögren's syndrome, diabetes mellitus, malignant disease.
3. Less than four real teeth (regardless of the third-largest molars)
4. Received periodontal treatment in the last 3 months
5. Pregnancy, breastfeeding

Date of first enrolment
01/10/2012

Date of final enrolment
31/08/2013

Locations

Countries of recruitment
Viet Nam

Study participating centre
Cho Ray Hospital
Department of Rheumatology
201B Nguyen Chi Thanh
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Sponsor information

Organisation
Ho Chi Minh City Medicine and Pharmacy University

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Sponsor type
University/education

Website
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ROR
https://ror.org/025kb2624

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
The protocol and study data are being prepared for publication. Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
30/07/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Van Bich Nguyen (nbvan@ump.edu.vn). Type of data: raw outcomes of the interventions. When: after publication. Data will be shared with other research groups belong to a university or institute (not for individuals) with reasonable requests (for study purpose only). Means: direct email. No patient information will be shared (by ethical or legal restrictions).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2020	18/08/2020	Yes	No