ISRCTN79186420 https://doi.org/10.1186/ISRCTN79186420

Experimental study of periodontitis and rheumatoid arthritis

Submission date
12/10/2011

Recruitment status
No longer recruiting

Registration date
20/03/2012

Overall study status
Completed

Last Edited
19/02/2021

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Rheumatoid arthritis is a long-term (chronic) disease where the body's immune system attacks the cells that line the joints by mistake, making them swollen, stiff and painful, and over time damaging the joint, cartilage and nearby bone. Periodontitis is a very common condition where the gums become swollen, sore or infected, leading to bleeding, loss of the tissue supporting the teeth, and tooth loss. Some studies have suggested a possible link between rheumatoid arthritis and periodontitis. The aim of this study is to assess the effectiveness of periodontal treatment at reducing rheumatoid arthritis symptoms, in patients suffering from both periodontitis and rheumatoid arthritis.

Who can participate?
Patients aged 18 or over with both rheumatoid arthritis and periodontitis

What does the study involve?
Participants' periodontitis and rheumatoid arthritis symptoms are assessed at the first visit and they are randomly allocated to one of two groups to receive either immediate or delayed periodontal treatment. Periodontal treatment includes scaling to remove plaque and tartar from the teeth, root planing to clean under the gums and get rid of bacteria from the roots of the teeth, antibiotics, oral hygiene instructions and antiseptic mouthwash. Both groups attend a visit to strengthen their use of hygiene techniques 45 days later, and after another 45 days their periodontitis and rheumatoid arthritis symptoms are reviewed .

What are the possible benefits and risks of participating?
Participants may benefit from improved gum health and improved general health (reduction in rheumatoid arthritis symptoms, improved quality of life). The expected risks are those of periodontal treatment: sensitivity, gum recession, side effects of taking antibiotics, and dysgeusia (distortion of the sense of taste).

Where is the study run from?
Toulouse University Hospital - Purpan and Bordeaux University Hospital - Pellegrin (France)

When is the study starting and how long is it expected to run for?
December 2011 to June 2013

Who is funding the study?
University Hospital of Toulouse - Hospital Clinical Research Programme (France)

Who is the main contact?
Dr Jean-Noël Vergnes
jn.vergnes@free.fr

Contact information

Type(s)
Scientific

Contact name
Dr Jean-Noel Vergnes

Contact details
Faculty of Dental Surgery
CHU de Toulouse
3 Chemin des Maraîchers
Cedex 9
Toulouse
France
31400
-
vergnes.jn@chu-toulouse.fr

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PHRC 10.046.08

Study information

Scientific Title
Efficacy of therapeutic management of periodontitis on the clinical manifestations of rheumatoid arthritis: a randomized controlled trial

Acronym
ESPERA

Study objectives

1. To assess the effectiveness of periodontal treatment to reduce the severity of rheumatoid arthritis (RA), in patients suffering from both periodontitis and rheumatoid arthritis
2. Periodontal treatment reduce the severity of rheumatoid arthritis

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Committee for Protection of Research Subjects (Comité de Protection des Personnes [CPP]), Sud-Ouest Outre-Mer I, 11/07/2011
2. Sanitary Safety in Health Products Agency (Agence française de sécurité sanitaire des produits de santé [AFSSAPS]), 04/11/2010, ref: 2010-A00533-36

Study design
Randomized controlled clinical 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 the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Rheumatoid arthritis and periodontitis

Interventions
A rheumatologist will assess periodontal and RA parameters at the first visit (V1), then the participants will be randomly assigned to one of two groups to receive immediate or delayed periodontal treatment.

Periodontal treatment will include non-surgical scaling and root planing, systemic antibiotherapy, oral health instructions and antiseptic prescription.

For the immediate treatment group, a dentist will perform periodontal treatment (V2) and will strengthen the implementation of hygiene techniques 45 days later (V3).

The delayed treatment group will receive periodontal treatment at V4, strengthening of hygiene measures 45 days later (V5), and rheumatological and periodontal reassessment after 45 days (V6). Thus, periodontal care will be equivalent in the 2 groups.

Periodontal and rheumatological features will be reviewed 45 days after V3 (at V4) for both groups. Variation between V1 and V4 will be compared between the two groups.

Intervention Type
Mixed

Primary outcome measure
Difference between 3-month and baseline DAS 28 scores

Secondary outcome measures
Difference between 3-month and baseline values of the following:
1. American College of Rheumatology (ACR) scores
2. Health Assessment Questionnaire (HAQ) scores
3. General Oral Health Assessment Index (GOHAI) scores
4. Periodontal Inflamed Surface Area (PISA)

Overall study start date
01/12/2011

Completion date
30/06/2013

Eligibility

Key inclusion criteria
1. Male or female, aged 18 years or older
2. Rheumatoid arthritis diagnosed since at least one year
3. Disease Activity Score (DAS 28) score between 3.2 and 5.1
4. No change to medication, dosage or formulation in RA treatment during the 3 months before the inclusion visit
5. At least six natural teeth with root
6. Subject with periodontitis, defined by the presence of one site with periodontal probing depth ≥ 4 mm and clinical attachment level ≥ 3 mm on at least 4 teeth
7. Subject able to understand and willing to provide written informed consent in French
8. Subject affiliated to the security system

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

40

Total final enrolment
22

Key exclusion criteria
1. Acute oral infection, acute oral pain (including pulpitis), suspicious oral mucosal lesion, severe oral inflammation unrelated to periodontal conditions, or need for immediate tooth extractions
2. Planned hospitalization within 4 months after the screening visit
3. One or more known infectious diseases [Human immunodeficiency virus(HIV), hepatitis, infectious mononucleosis]
4. Known clinically significant renal disease (creatinine clearance <60 ml/min), or liver disease
5. Unbalanced diabetes
6. Known risk of endocarditis
7. Have a permanent pacemaker
8. Antithrombotic treatment
9. Severe difficulties in understanding written and spoken French
10. Pregnant, lactating, or plans to become pregnant during the study
11. Chronic disorder that requires chronic or intermittent use of antibiotics
12. Hypersensitivity to chlorhexidine gluconate
13. Participation in another study with an investigational compound
14. Contraindications to both amoxicillin and clindamycin
15. Contraindications to dental local anesthetic

Date of first enrolment
01/12/2011

Date of final enrolment
30/06/2013

Locations

Countries of recruitment
France

Study participating centre
University Hospital of Toulouse (CHU de Toulouse)
Toulouse
France
31400

Sponsor information

Organisation
University Hospital of Toulouse (CHU de Toulouse) (France)

Sponsor details
Directorate of Research and Innovation
Hôtel Dieu
2 Rue Viguerie
Cedex 9
Toulouse
France
31059
-
algans.n@chu-toulouse.fr

Sponsor type
Hospital/treatment centre

Website
http://www.chu-toulouse.fr/

ROR
https://ror.org/017h5q109

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospital of Toulouse - Hospital Clinical Research Programme [CHU Toulouse - Programme Hospitalier de Recherche Clinique] (France) ref: 1004608

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?
Protocol article	protocol	14/08/2013		Yes	No

Results article	results	01/10/2019	19/02/2021	Yes	No