

Experimental study of periodontitis and rheumatoid arthritis

Submission date 12/10/2011	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 20/03/2012	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 19/02/2021	Condition category Musculoskeletal Diseases	☐ 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

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

Difference between 3-month and baseline DAS 28 scores

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

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

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	01/10/2019	19/02/2021	Yes	No
Protocol article	protocol	14/08/2013		Yes	No