

# Outcomes of Periodontal Therapy in Rheumatoid Arthritis (OPERA)

<b>Submission date</b> 05/06/2014	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 05/06/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 27/01/2020	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
11940

## Study information

**Scientific Title**

Outcomes of Periodontal Therapy in Rheumatoid Arthritis (OPERA)

**Acronym**

Outcomes of Periodontal Therapy in Rheumatoid Arthritis (OPERA)

**Study objectives**

Rheumatoid arthritis (RA) is common chronic inflammatory disease that is characterised by inflammation in the joints ultimately leading to joint destruction and consequently functional impairment and disability. In addition, patients with RA are more likely to develop cardiovascular diseases such as heart disease and stroke and are therefore at an increased risk of premature death.

Several studies now indicate that chronic periodontitis, a common inflammatory disease of the gums surrounding the teeth caused by bacteria in the mouth, can initiate and worsen inflammation in RA. A small number of small clinical studies in patients with RA have indicated that periodontal therapy aimed at eliminating gum infection can reduce joint and systemic inflammation in patients with RA. We therefore propose this clinical study to study the effects of an intensive periodontal therapy administered by a dental hygienist in a secondary care setting to patients with RA who also suffer from moderate to severe periodontitis.

We will measure the effect of this intervention on several clinical and blood measures of RA and RA activity as well as on overall and oral health related quality of life. We will also assess how easy or difficult it is to recruit patients into such a study and how easy and acceptable patients find participation and compliance with the periodontal therapy and the study procedures.

We plan to evaluate this intervention in a larger definitive study, provided that the proposed pilot study is successful and shows promising results. If successful, treatment of gum disease in patients with RA could be an inexpensive and safe, non-pharmacological treatment with direct benefit for patients with RA in terms of RA severity and progression.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

11/WM/0235

**Study design**

Randomised; Interventional; Design type: Not specified, Treatment

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

## Participant information sheet

### Health condition(s) or problem(s) studied

Topic: Musculoskeletal disorders, Oral and dental health; Subtopic: Musculoskeletal (all Subtopics), Oral and dental health; Disease: Inflammatory Arthritis

### Interventions

Periodontal Therapy, Intensive periodontal therapy administered by a Dental Hygienist; Study Entry : Registration and One or More Randomisations

### Intervention Type

Other

### Phase

Not Applicable

### Primary outcome measure

Outcome evaluations will include measures of RA disease activity and disability, periodontal measure

### Secondary outcome measures

Not provided at time of registration

### Overall study start date

01/04/2013

### Completion date

31/03/2015

## Eligibility

### Key inclusion criteria

1. Able and willing to give written informed consent and comply with the requirements of the study protocol
2. Age 18+ years
3. Patients with rheumatoid arthritis (RA) diagnosed according to the revised 1987 ACR criteria for the classification of RA
4. DAS28 score  $\leq 3.2$
5. DAS28 score  $> 5.1$  only if patient on biologics or patient unwilling to take biologics
6. Treatment with DMARD for  $\geq 3$  months and stable dose for  $\geq 2$  months OR patient refusing to use DMARD
7. Generalized moderate to severe chronic periodontitis as evidenced by pocketing with clinical attachment loss (CAL  $\geq 4$  mm on at least 2 non-adjacent teeth AND cumulative probing depth  $\geq 40$  mm). The threshold based on CAL is consistent with a recently proposed case definition. Cumulative pocket depth is the sum of the deepest probing depths of at least 4 mm on each tooth. The proposed threshold ensures a minimum number of teeth with deep periodontal pockets, e.g., a patient who has 8 teeth with 5 mm pockets would meet this criterion.

### Participant type(s)

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

Planned Sample Size: 60; UK Sample Size: 60

**Key exclusion criteria**

1. Rheumatic autoimmune disease other than RA, or significant systemic involvement secondary to RA (including but not limited to vasculitis, pulmonary fibrosis or Felty's syndrome). Secondary Sjögren's syndrome or secondary limited cutaneous vasculitis with RA is permitted.
2. History of, or current, inflammatory joint disease other than RA (including, but not limited to, gout, reactive arthritis, psoriatic arthritis, seronegative spondyloarthropathy) or other systemic autoimmune disorder (including, but not limited to, systemic lupus erythematosus, inflammatory bowel disease, scleroderma, inflammatory myopathy, mixed connective tissue disease or any overlap syndrome).
3. Diagnosis of juvenile idiopathic arthritis (JIA) or juvenile rheumatoid arthritis (JRA) and/or RA before age 16.
4. Any surgical procedure, including bone/joint surgery/synovectomy (including joint fusion or replacement) within 12 weeks prior to baseline or planned during study
5. Significant concomitant disease, which would preclude patient participation in the investigators opinion.
6. Intra-articular or parenteral glucocorticoids within 4 weeks prior to baseline
7. Any dental condition that would preclude, in the investigators opinion, participation in the trial (including but not limited to restorations impairing oral hygiene or instrumentation, need for extractions or extensive restorative work)
8. Periodontal treatment (surgical or nonsurgical, excluding supragingival cleanings) within 12 months prior to baseline
9. Previous participation in a CTIMP within the past 4 months

**Date of first enrolment**

01/04/2013

**Date of final enrolment**

31/03/2015

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**  
School Of Dentistry , St. Chads Queensway  
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## **Sponsor information**

**Organisation**  
University of Birmingham (UK)

**Sponsor details**  
Edgbaston  
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**Sponsor type**  
University/education

**ROR**  
<https://ror.org/03angcq70>

## **Funder(s)**

**Funder type**  
Government

**Funder Name**  
NIHR Research for Patient Benefit (RfPB); Grant Codes: PB-PG-0609-19100

## **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?
<a href="#">Results article</a>	results	01/10/2019	27/01/2020	Yes	No