ISRCTN52833273 https://doi.org/10.1186/ISRCTN52833273

Outcomes of Periodontal Therapy in Rheumatoid Arthritis (OPERA)

Submission date	Recruitment status	[ ] Prospectively registered
05/06/2014	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
05/06/2014	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
27/01/2020	Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Thomas Dietrich

Contact details
School Of Dentistry , St. Chads Queensway
Birmingham
United Kingdom
B4 6NN
-
t.dietrich@bham.ac.uk

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 =3.2
5. DAS28 score >5.1 only if patient on biologics or patient unwilling to take biologics
6. Treatment with DMARD for = 3 months and stable dose for = 2 months OR patient refusing to use DMARD
7. Generalized moderate to severe chronic periodontitis as evidenced by pocketing with clinical attachment loss (CAL>=4 mm on at least 2 non-adjacent teeth AND cumulative probing depth >=40mm). 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 4mm 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 5mm 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 Feltys syndrome). Secondary Sjögrens 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, articipation 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
Birmingham
United Kingdom
B4 6NN

Sponsor information

Organisation
University of Birmingham (UK)

Sponsor details
Edgbaston
Birmingham
England
United Kingdom
B15 2TT

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?
Results article	results	01/10/2019	27/01/2020	Yes	No