

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Effect of Non surgical Periodontal Treatment on the Severity of Rheumatoid Arthritis(RA)

Protocol summary

Study aim

Determination of non-surgical Periodontal treatment impacts on Rheumatoid Arthritis disease severity

Design

Randomized one side blinded clinical trial with controlled group

Settings and conduct

Referred persons to Vali-Asr educational curative hospital in Birjand. This randomized clinical trial studied on 60 patients that are infected to Rheumatoid Arthritis (based on Euler criteria consist of number and type of engaged joint, ESR & CRP inflammation factors, Serologic factors like RF & Anti CCP and illness duration that should gain at least 6 points totally) and mild to moderate periodontal disease based on visual examination (positive BOP, marginal inflammation, plaque and scale and lost teeth) that are confirmed by dentist. Patients are divided into 3 groups (1. under scaling and Antibiotic therapy 2. just under scaling therapy 3. witness). at the beginning and end of study, DAS 28 questionnaire will be filled for all 3 groups.

Participants/Inclusion and exclusion criteria

Criteria for entering the study: 1. People older than 18 years 2. Patients that are afflicted to Arthritis disease according to ACR-Eulur criteria 3. Passed at least a year since RA diagnosis 4. Disease infection to gum inflammation with mild to moderate severity 5. Have at least six healthy teeth 6. Not infected to other systemic disease like Leukemia, Diabetes and White blood cell deficiency 7. No Smoking 8. Non-use of effective medicines on Gum Cognitive tissue properties like Nifedipine and Cortico steroids 9. Non-use of Antibiotics over the past 3 months 10. No periodontal treatments over the past 6 months Exit criteria: 1- Complications 2- Change in the diet during the study period 3. Having systemic diseases such as leukemia, diabetes, white blood cell deficiency, anemia,

Intervention groups

1. Dental scaling 2. Dental scaling and drug therapy

Main outcome variables

RF-CRP-ESR-DAS-Amoxicillin

General information

Reason for update

Acronym

-

IRCT registration information

IRCT registration number: **IRCT20180613040084N1**

Registration date: **2018-10-10, 1397/07/18**

Registration timing: **retrospective**

Last update: **2018-10-10, 1397/07/18**

Update count: **0**

Registration date

2018-10-10, 1397/07/18

Registrant information

Name

Marzie Talaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

marzie.talaei@bums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-20, 1396/10/30

Expected recruitment end date

2018-04-03, 1397/01/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effect of Non surgical Periodontal Treatment on the Severity of Rheumatoid Arthritis(RA)

Public title
Effect of dental scaling on Arthritis (RA)

Purpose
Health service research

Inclusion/Exclusion criteria
Inclusion criteria:
 Passed at least a year since RA diagnosis and disease activity score should be between 1.5 to 3.2 Disease infection to gum inflammation with mild to moderate severity Have at least six healthy teeth Not infected to other systemic disease like Leukemia, Diabetes and White blood cell deficiency No smoking Non-use of effective medicines on Gum Cognitive tissue properties like Nifedipine and Cortico steroids Non-use of Antibiotics over the past 3 months No periodontal treatments over the past 6 months
Exclusion criteria:
 infection to systemic disease like Leukemia, Diabetes, White blood cell deficiency, Anemia, Nephropathy, Hepatopathy, AIDS, having Pacemaker and Infectious Endocarditis

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Random numbers table Each member was assigned a number, then the numbers were written on paper, and for each group, 20 numbers were selected.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics committee of Birjand University of Medical Sciences کمیته اخلاق دانشگاه علوم پزشکی بیرجند
Street address
 Dentistry faculty, Birjand University of Medical Sciences, Ghaffari street, Birjand, Iran دانشکده دندان پزشکی، دانشگاه علوم پزشکی بیرجند، خیابان غفاری، بیرجند، ایران
City
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Province
 South Khorasan
Postal code
 ۹۷۱۷۸۵۳۵۷۷
Approval date
 2018-03-09, 1396/12/18
Ethics committee reference number
 Ir.bums.REC.1396.353

Health conditions studied

1

Description of health condition studied
 Periodontitis_Rheumatoid Arthritis(RA)
ICD-10 code
 M05
ICD-10 code description
 Rheumatoid arthritis with rheumatoid factor

Primary outcomes

1

Description
 Improvement of rheumatic pains
Timepoint
 Record swelling and pain of rheumatic patients at the beginning of the study (before dental scaling), 45 and 90 days after scaling
Method of measurement
 Questionnaire 28 das (disease activity score)

Secondary outcomes
 empty

Intervention groups

1

Description
 Intervention group:
Category
 Treatment - Other

2

Description

Intervention group:
Category
Treatment - Drugs

3

Description
Control group:
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Birjand University of Medical Sciences
Full name of responsible person
Marzie Talaei
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Birjand University of Medical Sciences
Proportion provided by this source

100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Birjand University of Medical Sciences
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Narjes Akbari
Position
Assistant Professor
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Person responsible for updating data

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Full name of responsible person

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Other areas of specialty/work

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Fax**Email**

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Because its not mandatory yet

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Publication of a paper in academic journals

When the data will become available and for how long

From 2019

To whom data/document is available

Anyone who wishes to access the data.

Under which criteria data/document could be used

To achieve the aims in the approved proposal.

From where data/document is obtainable

Proposal may be submitted up to 24 months following article publication

What processes are involved for a request to access data/document

Proposal will be available up to 24 months following article publication.

Comments