

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

The effect of the treatment of periodontitis on rheumatoid arthritis disease activity in patients who referred to Rheumatology clinic, Semnan

Protocol summary

Summary

Objective: Assessing the effect of periodontal treatment on rheumatoid arthritis activity based on disease activity score, ESR and CRP. Study design: clinical trial, not blind, unicenter, phase three. The study population: patients with rheumatoid arthritis and periodontitis simultaneously who were selected randomly. Inclusion criteria: 18 years and older; diagnosis of RA at least one year ago; disease activity score between 3.2 and 5.1; having at least six natural teeth; the patient be educable; having gingivitis with mild to moderate degree. The exclusion criteria were: risk of infection; serious liver or kidney diseases; chronic infectious disease that needs to frequent use of antibiotics; uncontrolled diabetes; taking anti-thrombotic and biologic therapy; sensitivity to chlorhexidine gluconate (oral rinse); contraindication of amoxicillin and metronidazole; severe oral problems which requiring immediate surgery; pregnancy, breast-feeding or if want to get pregnant during the study period; any febrile or chronic diseases. Sample Size: The sample size is 30. Interventions: At first, DAS-28 questionnaire filled and if periodontitis confirmed by dentist, treatment initiated which includes non surgical scaling, root planning, systemic antibiotics, antiseptic (chlorhexidine) and oral health education. At the end of treatment period and confirming of complete remission by dentist, on days 45 and 90 after initiation all patients will be visited by rheumatologist and DAS-28 questionnaire completed again. ESR and CRP are also measured at each visit in a reference laboratory. Time of Intervention: at first day and 45 and 90 days later re-evaluation is done by a rheumatologist. The primary outcome or consequences of the study: improvement of rheumatoid arthritis activity score and lowering of ESR and CRP level.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015122512823N3**

Registration date: **2016-01-04, 1394/10/14**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-01-04, 1394/10/14

Registrant information

Name

Jamileh Moghimi

Name of organization / entity

Semnan University of Medical Science

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Semnan University of Medical Sciences

Expected recruitment start date

2016-01-05, 1394/10/15

Expected recruitment end date

2016-07-04, 1395/04/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of the treatment of periodontitis on

rheumatoid arthritis disease activity in patients who referred to Rheumatology clinic, Semnan

Public title

The effect of the treatment of periodontitis on rheumatoid arthritis disease activity

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: 18 years and older; diagnosis of RA at least one year ago; disease activity score between 3.2 and 5.1; having at least six natural teeth; the patient be educable; having gingivitis with mild to moderate degree. The exclusion criteria were: risk of infection; serious liver or kidney diseases; chronic infectious disease that needs to frequent use of antibiotics; uncontrolled diabetes; taking anti-thrombotic and biologic therapy; sensitivity to chlorhexidine gluconate (oral rinse); contraindication of amoxicillin and metronidazole; severe oral problems which requiring immediate surgery; pregnancy, breast-feeding or if want to get pregnant during the study period; any febrile or chronic diseases.

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee of Semnan University of Medical Sciences

Street address

Basidj Boulevard

City

Semnan

Postal code

3519747167

Approval date

2015-12-01, 1394/09/10

Ethics committee reference number

IR.SEMUMS.REC.1394.122

Health conditions studied

1

Description of health condition studied

Periodontitis

ICD-10 code

K05.3

ICD-10 code description

Chronic periodontitis

2

Description of health condition studied

Rheumatoid arthritis

ICD-10 code

M06.9

ICD-10 code description

Rheumatoid arthritis, unspecified

Primary outcomes

1

Description

Rheumatoid arthritis activity

Timepoint

Before initiation of interventions, 45 and 90 days after intervention

Method of measurement

DAS-28 questionnaire

Secondary outcomes

1

Description

Erythrocyte Sedimentation Rate

Timepoint

Before initiation of interventions, 45 and 90 days after intervention

Method of measurement

Laboratory test

2

Description

C- reactive protein

Timepoint

Before initiation of interventions, 45 and 90 days after intervention

Method of measurement

Laboratory test

Intervention groups

1

Description

Interventions: At first, DAS-28 questionnaire filled and if periodontitis confirmed by dentist, treatment initiated which includes non surgical scaling, root planning, systemic antibiotics (metronidazole 500 mg three times per day and amoxicillin 500 mg three times per day for a ten days period), antiseptic (Chlorhexidine gluconate oral rinse 0.12% 2 times per day) and oral health education. At the end of treatment period, on 20th day of study all patients will be visited by dentist and if he confirms complete remission, on days 45 and 90 after initiation all patients will be visited by rheumatologist and DAS-28 questionnaire completed again. ESR and CRP are also measured at each visit in a reference laboratory

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Kowsar Hospital

Full name of responsible person

Dr. Amir Hassani

Street address

Basidj Boulevard, Amin Avenue

City

Semnan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Mohammad Reza Asgari

Street address

Basij Bulvard

City

Semnan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Semnan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Dr. Jamileh Moghimi

Position

Rheumatologist/ Associate Professor

Other areas of specialty/work

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Person responsible for scientific inquiries

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Position

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty