Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 is 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

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Name of organization / entity
Semnan University of Medical Science
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Iran (Islamic Republic of)
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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 Commettee of Semnan University of Medical Sicenses
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 is includes non surgical scaling, root planning, systemic antibiotics (metronidazole 500 mg three time per day and amoxicillin 500 mg three time per day for a ten days period), antiseptic (Chlorhexidine gluconate oral rinse 0.12% 2 time 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 confirm 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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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