Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison between periodontal interventions with oral health care on the disease activity in Systemic Lupus Erythematosus

Protocol summary

Summary

The current protocol was aimed to investigate the effect of periodontitis treatment on the disease activity in Systemic Lupus Erythematosus. Patients were randomly allocated into two groups of intervention and control using block allocation method (block size 4). The intervention group depends on the severity of the periodontal disease received oral health education or dental scaling and oral health education or 500 mg amoxicillin and 250 mg metronidazole three times per day for 10 day along with dental scaling and oral health education. In the control group, dental hygiene and refer for treatment was recommended. This study was single blind that person who evaluate disease activity in Systemic Lupus Erythematosus was not aware of patients assigned to groups. Inclusion criteria were as follow: Systemic Lupus Erythematosus disease activity index (SELDAI) equal or greater to 2. Exclusion criteria were considered as: Changes in the patient's treatment schedule by increasing the dose or adding another Immunosuppression drug; periodontitis along with other problems including tooth filling; suffering from Rheumatoid Arthritis, diabetes; smoking; medication that lead gum become greater than normal; gum bleeding; changes in the form of alveolar bone. Disease activity was evaluated using SELDAI that included immunological laboratory findings and clinical manifestations of the disease.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017071610340N17**
Registration date: **2017-07-24, 1396/05/02**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-07-24, 1396/05/02

Registrant information

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Name of organization / entity
Golestan University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Golestan University of Medical Science

Expected recruitment start date

2015-03-21, 1394/01/01

Expected recruitment end date

2017-03-19, 1395/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between periodontal interventions with oral health care on the disease activity in Systemic Lupus Erythematosus

Public title

The effect of dental interventions on the disease activity in Systemic Lupus Erythematosus

Purpose

Prevention

Inclusion/Exclusion criteria
Inclusion criteria were as follow: Systemic Lupus Erythematosus disease activity index (SELDAI) equal or greater to 2. Exclusion criteria were considered as: Changes in the patient's treatment schedule by increasing the dose or adding another Immunosuppression drug; periodontitis along with other problems including tooth filling; suffering from Rheumatoid Arthritis, diabetes; smoking; medication that lead gum become greater than normal; gum bleeding; changes in the form of alveolar bone.
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features
Person who evaluate disease activity in Systemic Lupus Erythematosus was not aware of patients assigned to groups

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic Committee of Golestan University of Medical Science
Street address
4 Kilometer of Gorgan-sari Road, Falsafi educational campus, Vice Chancellor of Technology and Information, Gorgan
City
Gorgan
Postal code
Approval date
2017-07-02, 1396/04/11
Ethics committee reference number
IR.GOUMS.REC.1396.37

Health conditions studied

1

Description of health condition studied
Systemic lupus erythematosus
ICD-10 code
M32
ICD-10 code description
Systemic lupus erythematosus

Primary outcomes

1

Description
disease activity in Systemic Lupus Erythematosus
Timepoint
Three month after intervention
Method of measurement
blood sample

Secondary outcomes

1

Description
Periodontal Assessment
Timepoint
Three month after intervention
Method of measurement
Physical examination

Intervention groups

1

Description
The intervention group received oral health education
Category
Behavior

2

Description
The intervention received dental scaling and oral health education
Category
Treatment - Other

3

Description
The intervention group received 500 mg amoxicillin and 250 mg metronidazole three times per day for 10 day along with dental scaling and oral health education
Category
Treatment - Other

4

Description

In the control group, dental hygiene and refer for treatment was recommended

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sayyad Shirazi Hospital

Full name of responsible person

Hasan Karimi

Street address

Shahid Sayyad Shirazi Hospital, Shahid Sayyad Shirazi Street, Gorgan City, Golestan Province

City

Gorgan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Golestan University of Medical Sciences

Full name of responsible person

Mohsen Saeedi

Street address

4 Kilometer of Gorgan-Sari Road, Falsafi educational campus, Vice chancellor for research, Gorgan

City

Gorgan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Golestan 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

Golestan University of Medical Science

Full name of responsible person

Hasan Karimi

Position

Internist

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

Mohamma Aryaie

Position

MSc in Epidemiology

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