

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 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

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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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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