

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Evaluating the effect of non surgical periodontal treatment on the severity of systemic lupus erythematosus in patients referred to the Department of Rheumatology of Shahid Sadoughi and Rahnemon Hospitals

Protocol summary

Study aim

Determining the effect of non-surgical periodontal treatments on the severity of systemic lupus erythematosus

Design

Clinical trial with control group, single blind, randomized, 90 eligible patients are divided into two groups using a random number table

Settings and conduct

This study will be performed in patients referred to the rheumatology department of Shahid Sadoughi and Rahnemoun hospitals in Yazd, who simultaneously suffer from systemic lupus erythematosus (SLE) and periodontitis. Record the percentage of areas with bleeding during probing and plaque index will be evaluated. Then the severity of SLE activity is recorded by calculating the SLE activity index as well as the laboratory results of acute phase reactive protein (CRP) and erythrocyte sedimentation rate (ESR). In the intervention group, scaling treatment and root surface leveling are performed. After 3 months, the variables in both groups are evaluated as at the beginning of the study, and finally the comparison between the control and experimental groups in terms of this specific index is done.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Definitive confirmation of systemic lupus erythematosus by a fellow rheumatologist, confirmation of moderate to severe generalized chronic periodontitis, no use of any antibiotics during 3 months before the start of the study. Exclusion criteria: having another systemic disease, history of periodontal treatment in the last 6 months, smoking

Intervention groups

Patients are randomly divided into two groups (intervention group undergoing scaling treatment and

health education and control group without periodontal treatment)

Main outcome variables

Probing depth, Clinical attachment loss ,Bleeding index, Plaque index, Systemic lupus erythematosus index and laboratory results of acute phase reactive protein (CRP) and erythrocyte sedimentation rate (ESR)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151013024509N4**

Registration date: **2021-03-23, 1400/01/03**

Registration timing: **registered_while_recruiting**

Last update: **2021-03-23, 1400/01/03**

Update count: **0**

Registration date

2021-03-23, 1400/01/03

Registrant information

Name

Fahimeh Rashidi Maybodi

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-21, 1400/01/01

Expected recruitment end date

2021-06-22, 1400/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of non surgical periodontal treatment on the severity of systemic lupus erythematosus in patients referred to the Department of Rheumatology of Shahid Sadoughi and Rahnemon Hospitals

Public title

Evaluating the effect of non surgical periodontal treatment on the severity of systemic lupus erythematosus

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Definitive confirmation of systemic lupus erythematosus by a fellow rheumatologist and the condition of the disease is controlled Confirmation of moderate to severe generalized chronic periodontitis Have at least 20 teeth There is no evidence of heart valve involvement, congenital disorder, or a history of previous endocarditis requiring antibiotic prophylaxis. The patient's dose of corticosteroids should be below 20 mg of hydrocortisone or its equivalent A recent blood test is available based on the patient's neutrophil count above 1000 Evaluation of coagulation factors in case of thrombocytopenia in the patient's blood test Not taking aspirin and anticoagulants in the last month Do not take any antibiotics for 3 months before the start of the study Do not take a cytotoxic drug such as cyclophosphamide in the last month Non-long-term use of drugs affecting periodontal status (anticonvulsants, calcium channel blockers, etc.) during the 3 months before the start of the study Complete the consent form

Exclusion criteria:

Having another systemic disease such as primary Sjogren's syndrome, diabetes, cardiovascular disease, history of radiation therapy or chemotherapy Antiphospholipid syndrome Pregnancy in a recent year History of periodontal treatment in the last 6 months Smoking

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: 90

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization Patients will be divided into control and intervention groups using simple random allocation method and random number table. Randomization tool: Through the website <https://www.graphpad.com/quickcalcs/randomize1/>, the total sample size is 90 people who were randomly divided into two groups of 45 people and a random table was provided to the researcher and based on it. The control and intervention group is determined. The randomization process is performed by the study methodology consultant and clinical researchers are not aware of the randomization process and will not have the authority to change or predict the status of individuals.

Blinding (investigator's opinion)

Single blinded

Blinding description

The person evaluating the activity index of lupus erythematosus is not aware of the allocation of patients to intervention and control groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Shahid Sadoughi University of Medical Sciences, Yazd

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Shahid Bahonar Square

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Postal code

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Approval date

2019-06-25, 1398/04/04

Ethics committee reference number

IR.SSU.REC.1398.059

Health conditions studied**1****Description of health condition studied**

Systemic lupus erythematosus

ICD-10 code

M32.9

ICD-10 code description

Primary outcomes

1

Description

Probing depth

Timepoint

At the beginning of the study (before the intervention) and 3 months after the start of the study

Method of measurement

With Williams Probe

2

Description

Clinical attachment loss

Timepoint

At the beginning of the study (before the intervention) and 3 months after the start of the study

Method of measurement

With Williams Probe

3

Description

Bleeding index

Timepoint

At the beginning of the study (before the intervention) and 3 months after the start of the study

Method of measurement

Percentage of bleeding around the entire teeth after 30 seconds after probing

4

Description

Plaque index

Timepoint

At the beginning of the study (before the intervention) and 3 months after the start of the study

Method of measurement

Percentage of plaque accumulation around tooth surfaces after evaluation with a disclosing agent

5

Description

Systemic lupus erythematosus disease activity index

Timepoint

At the beginning of the study (before the intervention) and 3 months after the start of the study

Method of measurement

Numerically from 0 to 105 with Q * MD software

6

Description

C-Reactive protein (CRP)

Timepoint

At the beginning of the study (before the intervention) and 3 months after the start of the study

Method of measurement

Record patient test information

7

Description

Erythrocyte Sedimentation Rate (ESR)

Timepoint

At the beginning of the study (before the intervention) and 3 months after the start of the study

Method of measurement

Record patient test information

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 45 patients with moderate to severe chronic periodontitis, at the beginning of the intervention, complete periodontal examinations, scaling and smoothing of root surfaces, Bass technique toothbrushing training with a dental model and a dental model in 10 minutes, registration Laboratory data of acute phase reactive protein (CRP) and erythrocyte sedimentation rate (ESR) and evaluation and recording of systemic lupus erythematosus activity index with Q * MD software, three months later examination and re-registration of the mentioned information.

Category

Treatment - Other

2

Description

Control group: The control group includes patients who are only trained in brushing with Bass technique by lecture method and with a dental model for 10 minutes.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sadoughi Hospital, Yazd

Full name of responsible person

Dr. Hamidreza Bashiri

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2

Recruitment center

Name of recruitment center
Shahid Rahnemoun Hospital
Full name of responsible person
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3

Recruitment center

Name of recruitment center
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Full name of responsible person
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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

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Fahimeh Rashidi

Position

Periodontist

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

Kimiya Sezavar

Position

Resident Periodontics

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

Contact

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Kimiya Sezavar

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Accurate data collection method: In this study, periodontal status and severity of systemic lupus erythematosus for each patient at the beginning and after three months of treatment are evaluated based on the following clinical and laboratory parameters: Envelope depth, Clinical Attachment loss, bleeding index and plaque. Evaluation of systemic lupus erythematosus disease activity index and acute phase reactive protein (CRP) and erythrocyte sedimentation rate (ESR) Data analysis method: After collecting the data, we encode them and enter them into the computer and are paired using SPSS 23 software and T-Tset tests and their independent or non-parametric equivalent and chi-square test and test. Fisher's exact results are analyzed.

When the data will become available and for how long

After collecting and analyzing data

To whom data/document is available

Executors of research projects

Under which criteria data/document could be used

If periodontal treatments affect the severity of SLE, because by providing effective solutions to improve oral health and more emphasis on hygiene, we can reduce the severity of SLE and impose heavier costs on the disease materially and Spiritual (qualitative) prevented.

From where data/document is obtainable

Executors of research projects

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

Requesting data requires the written consent of all research project implementers.

Comments