Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of non-surgical periodontal treatment on disease activity in patients with ankylosing spondylitis

Protocol summary

Study aim

Suggesting regular periodontal examinations and receiving SRP if the improvement of the condition of chronic periodontitis is effective on disease activity in patients with ankylosing spondylitis and periodontitis.

Design

In this study, 2 control groups will receive oral hygiene instructions only, while 2 treatment groups will receive a non-surgical periodontal intervention including SRP. Periodontal indices will be done in 6 and 12 weeks after the intervention, and after 12 weeks, the BASDAI index will be measured to investigate the effect of non-surgical periodontal treatment on the inflammatory condition of ankylosing spondylitis on the control group.

Settings and conduct

This clinical trial study was conducted on 96 patients with active ankylosing spondylitis and moderate to severe generalized chronic periodontitis who were referred to a rheumatology center and were assigned to four groups (24 people in each group) using the random block method. be. which include two general case groups (periodontal treatment) and control (no periodontal treatment).

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 18 years or older, confirmed diagnosis of active AS, moderate to severe diffuse chronic periodontitis, patients with at least 20 teeth.Exclusion criteria: taking antibiotics in a period of 3 months before the study, receiving non-surgical periodontal treatment in the last 6 months, smoking, severe liver or kidney failure, uncontrolled diabetes, heart disease, history of radiation therapy or chemotherapy, taking drugs with Possible effect on periodontium , severe dry mouth, pregnancy and breastfeeding patients who do not come to measure the investigated variables in the 6th and 12th weeks.

Intervention groups

2 treatment groups will receive a non-surgical periodontal intervention including SRP.

Main outcome variables

Bath Ankylosing Spondylitis Disease Activity(BASDAI)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161106030744N3**
Registration date: **2023-08-21, 1402/05/30**
Registration timing: **prospective**

Last update: **2023-08-21, 1402/05/30**
Update count: **0**

Registration date

2023-08-21, 1402/05/30

Registrant information

Name
Elham Fakhari

Name of organization / entity
Golestan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-02, 1402/06/11

Expected recruitment end date

2023-11-21, 1402/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of non-surgical periodontal treatment on disease activity in patients with ankylosing spondylitis

Public title

Evaluation of the effect of non-surgical periodontal treatment on disease activity in patients with ankylosing spondylitis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

18 years of age or older Confirmed diagnosis of active AS by a rheumatologist Moderate to severe generalized chronic periodontitis Patients who have at least 20 teeth

Exclusion criteria:

Antibiotic use in a period of 3 months before the study Received non-surgical periodontal treatment in the last 6 months smoking Severe liver or kidney failure Uncontrolled diabetes Heart disease History of radiation therapy or chemotherapy Taking drugs with a possible effect on the periodontium (such as cyclosporine, phenytoin, calcium channel blockers) Severe dry mouth Pregnancy and breastfeeding Patients who do not return to measure the investigated variables in the sixth and twelfth weeks

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

First, random blocks of eight containing four letters A, B, C, D (each letter is repeated twice) are generated, such as ABBDCACD. Then, among these 8 blocks, 12 blocks are randomly selected and a sequence of 96 is created, and each letter is placed in a sealed envelope, numbered from 1 to 96. These envelopes, which contain one of the letters A, B, C, D, are delivered by the rheumatologist to the qualified people. Only the generator of the random sequence of 96 knows about the contents of the envelopes. Patients go to the dental clinic with the envelopes and hand over the envelopes to the periodontist. People who have the letter A will be assigned to the first group and the letter B will be assigned to the second group and so on.

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

Golestan University of Medical Sciences

Street address

Gorgan - Hirkan Boulevard - Central Organization of Golestan University of Medical Sciences and Healthcare Services

City

gorgan

Province

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Postal code

4918936316

Approval date

2023-07-29, 1402/05/07

Ethics committee reference number

IR.GOUMS.REC.1402.132

Health conditions studied

1

Description of health condition studied

Periodontal disease - ankylosing spondylitis

ICD-10 code

Z40-Z54

ICD-10 code description

افرادی که برای رویه ها و مراقبت های بهداشتی خاص با خدمات بهداشتی مواجه می شوند

Primary outcomes

1

Description

Bath Ankylosing Spondylitis Disease Activity(BASDAI)

Timepoint

0_ 12 weeks after the intervention

Method of measurement

The BASDAI consists of a 0-10 scale (0 being no problem and 10 being the worst problem) that is used to answer 6 questions related to the 5 main AS symptoms.

Secondary outcomes

1

Description

Periodontal indices (PI, GI, PPD, GBI, CAL)

Timepoint

0_ 6 weeks after the intervention_ 12 weeks after the intervention

Method of measurement

CAL: The distance from Cej to the apical depth of the probe is in millimeters. GBI: whether probing causes bleeding (+) or not (-) is assessed. PPD: the distance from the free margin of the gingiva to the bottom of the sulcus depth in millimeters. GI: evaluation of the intensity and amount of gingival inflammation with BOP of the tooth. PI: It is based on the registration of soft debris and mineral deposits on the following teeth: upper right first molar, upper right lateral, upper left first premolar, lower left first molar, lower left lateral and lower right first premolar.

Intervention groups

1

Description

The first group: patients with AS and PD who take non-steroidal anti-inflammatory drugs (NSAID) who will receive non-surgical periodontal intervention including SRP. The second group: patients with AS and PD who take anti-tumor necrosis factor (TNF) drugs (with or without NSAID) who will receive non-surgical periodontal intervention including SRP

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

The office of Dr. Mehrdad Aghaei, specialist in rheumatology

Full name of responsible person

دکترمهرداد آقایی

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22 Adalat St., Valiasr St., 2nd floor, Saru building

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Dr.Narges Beigam Mirbehbahani

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beginning of shast kola road

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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

Gorgan 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

Gorgan University of Medical Sciences

Full name of responsible person

Dr Elham Fakhari

Position

assisstant professor Periodontics

Latest degree

Specialist

Other areas of specialty/work

Periodontics specialist

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Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available