

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jul 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3227 2253

##### Email address

dr.fakhari@goums.ac.ir

##### 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**  
Golestan  
**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

##### Street address

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

##### City

gorgan

##### Province

Golestan

##### Postal code

4916631757

##### Phone

+98 17 3233 5574

##### Email

info@drmehrdadaghaei.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Gorgan University of Medical Sciences

#### Full name of responsible person

Dr.Narges Beigam Mirbehbahani

#### Street address

beginning of shast kola road

#### City

gorgan

#### Province

Golestan

#### Postal code

49341-74515

#### Phone

+98 17 3245 1660

#### Email

mirbeh@goums.ac.ir

#### 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

assistant professor Periodontics

##### Latest degree

Specialist

##### Other areas of specialty/work

Periodontics specialist

##### Street address

gorgan-in front of Edalat 97-dentistry clinic of golestan university of medical science

##### City

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##### Postal code

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##### Email

Dr.fakhari@goums.ac.ir

## Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Gorgan University of Medical Sciences

#### Full name of responsible person

Dr Elham Fakhari

#### Position

assistant professor Periodontics

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Specialist

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## Web page address

## 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

## Person responsible for updating data

### Contact

#### Name of organization / entity

Gorgan University of Medical Sciences

#### Full name of responsible person

Dr Elham Fakhari

#### Position

assistant professor Periodontics