

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

A single blind randomized clinical trial to evaluate the effect of group training and supervised group exercise in patients with ankylosing spondylitis

Protocol summary

Study aim

Comparison of therapeutic efficacy of group training and supervised group exercise with routine treatments in patients with ankylosing spondylitis referred to Imam Khomeini Hospital Physical Medicine and Rehabilitation Clinic

Design

A randomized clinical trial with a sample size of 45 individuals and a single blinded and random number generator software will be used. This software generates a random number for each patient.

Settings and conduct

This study is a randomized clinical trial performed on patients with ankylosing spondylitis referred to Imam Khomeini Hospital Physical Medicine and Rehabilitation Clinic. Patients are divided into three equal and random groups. This study is a single blind study and the symptom assessor and the data analyzer will be unaware of the type of intervention performed for each patient. The first and second groups receive a two-hour training session on the disease and lifestyle according to the information in the manual by a trained physical medicine and rehabilitation specialist. The first group will then be supervised by a trained physiotherapist for 12 months for 12 one-hour sessions of exercise therapy. Patients are advised to continue their exercise program at home as much as possible. The second and third groups continue their usual treatments and are advised to do the exercises in the booklet at least three days a week for one hour each month.

Participants/Inclusion and exclusion criteria

definite diagnosis of Ankylosing spondylitis

Intervention groups

patients under 12 sessions of exercise therapy under the supervision of a skilled physiotherapist

Main outcome variables

Visual analogue scale (VAS), Questionnaires : Bath

Ankylosing Spondylitis Disease Activity Index(BASDAI), Bath Ankylosing Spondylitis Functional Index(BASMI), Ankylosing Spondylitis Disease Activity Score(ASDAS) and Evaluation of ankylosing spondylitis quality of life(EASiQoL).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191015045119N2**

Registration date: **2020-05-06, 1399/02/17**

Registration timing: **registered_while_recruiting**

Last update: **2020-05-06, 1399/02/17**

Update count: **0**

Registration date

2020-05-06, 1399/02/17

Registrant information

Name

Maryam Hosseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6619 2291

Email address

m_hosseini100@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-07-20, 1399/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A single blind randomized clinical trial to evaluate the effect of group training and supervised group exercise in patients with ankylosing spondylitis

Public title

Effect of education and exercise in patient with Ankylosing Spondylitis

Purpose

Other

Inclusion/Exclusion criteria**Inclusion criteria:**

The definitive diagnosis of Ankylosing Spondylitis in the age group of 18 to 65 years.

Exclusion criteria:

Cardiovascular Diseases such as Uncontrolled Blood Pressure, Vascular Aneurysms or Other Physical Activity Restrictions Absolute or relative contraindication for exercise

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done by block randomization. The following code is written on separated papers and dumped into the container. A paper will be taken for the patient who enters the clinic and the assignment of the next 6 patients will be specified. AABBC BBAACC BBCCAA CCBBA CCAABB

Blinding (investigator's opinion)

Single blinded

Blinding description

The data analyzer will be unaware of the intervention performed for each patient.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee on Biological Research

Street address

Imam Khomeini Hospital, Dr.Gharib Street, at the end of Keshavarz Boulevard

City

Tehran

Province

Tehran

Postal code

1419733141

Approval date

2019-06-19, 1398/03/29

Ethics committee reference number

IR.TUMS.IKHC.REC.1398.088

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

ankylosing spondylitis

ICD-10 code

M45

ICD-10 code description

Ankylosing spondylitis

Primary outcomes**1****Description**

Pain severity

Timepoint

1month, 2months, 6months

Method of measurement

Visual Analogue Scale index

2**Description**

Axial skeleton mobility including Cervical rotation, Chest expansion test, Modified schober's test, Lateral flexion test, Tragus-to-wall distance, Intermalleolar distance

Timepoint

1 months, 2 months, 6 months

Method of measurement

Using meter and unit of centimeters

3**Description**

Ankylosing spondylitis disease activity

Timepoint

1month, 2months, 6months

Method of measurement

Bath Ankylosing Spondylitis Disease Activity Index

questionnaire

4

Description

patients quality of life

Timepoint

1month, 2months, 6months

Method of measurement

Evaluation of Ankylosing Spondylitis Quality of Life questionnaire

5

Description

patients functional ability

Timepoint

1month, 2months, 6months

Method of measurement

Bath Ankylosing Spondylitis Functional Index questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: 15 people receiving a booklet, attending a disease training session and explaining the booklet and 12 sessions of exercise therapy supervised by a trained physiotherapist

Category

Rehabilitation

2

Description

Intervention group2: 15 people receiving a booklet, attending a disease training session and explaining the booklet

Category

Rehabilitation

3

Description

intervention group3: 15 people receiving a booklet

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital

Full name of responsible person

Doctor Maryam Hoseini

Street address

Bagherkhan street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammadali Sahraian MD

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Imam Khomeini Ave., Hasan Abad Sq., Sina Hospital

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Maryam Hosseini

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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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