Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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), Questionnairs : 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. AABBCC BBAACC BBCCAA CCBBAA 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 expantion 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
City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 6119 0111
Email
imamhospital@tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammadali Sahraian MD
Street address
Imam Khomeini Ave., Hasan Abad Sq., Sina Hospital
City
Tehran
Province
Tehran
Postal code
1417653761
Phone
+98 21 6670 6142
Fax
+98 21 6670 6141
Email
msahrai@tums.ac.ir
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
Street address
PM&R Department, Imam Khomeini Hospital, Towhid Square
City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 6619 2291
Fax
Email
m_hosseini100@yahoo.com

Person responsible for scientific 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
Street address
Imam Khomeini hospital, Dr. Gharib street, at the end of Kheshavarz boulevard
City
Tehran
Province
Tehran
Postal code
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Phone
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Email
m_hosseini100@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
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Maryam Hosseini
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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