Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of High-top shoes with Rocker sole on Pain, Disability, Activity Limitation and Vertical Ground Reaction Force in Rheumatoid Arthritis Patients

Protocol summary

Summary

The aim of this research was to study the effect of heel-to-toe rocker shoe on pain, disability, activity limitation, and vertical ground reaction force in patients with rheumatoid arthritis. In this clinical trial, 21 patients aged 20-65 with foot /ankle joint pain referred to Firozgar hospital and rheumatology clinics were recruited. VGRF with force plate and pain, disability, activity limitation with FFI questionnaire were assessed at the baseline, 1 week and 1 month after treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138812123101N2**
Registration date: **2010-05-08, 1389/02/18**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-05-08, 1389/02/18

Registrant information

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Mohamad Sadegh Ghasemi
Name of organization / entity
Iran University of Medical Science
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2008-12-05, 1387/09/15

Expected recruitment end date

2010-02-02, 1388/11/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of High-top shoes with Rocker sole on Pain, Disability, Activity Limitation and Vertical Ground Reaction Force in Rheumatoid Arthritis Patients

Public title

Effect of High-top shoes with Rocker sole on Pain, Disability, Activity Limitation and Vertical Ground Reaction Force in Rheumatoid Arthritis Patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: RA diagnosis according to the 1987 revised American College of Rheumatology (ACR) recommendations, Low DAS28, disease longer than one year, ability to walk without assistive devices, no use of other foot orthoses during the study, foot and/or ankle pain, Exclusion criteria: Previously undergone major joint surgery such as total joint arthroplasties and/or arthrodesesm, pregnancy, previously cortisone injection at 3 month prior to the study, presence of balance problems, skin lesions (ulcers, dermatitis), other systemic disease with relevant effects on walking ability, other joint deformities

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **21**

Randomization (investigator's opinion)

N/A

Randomization description

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

Ethics Committee of Faculty of Rehabilitation, Iran University of Medical Sciences

Street address

Rehabilitation collage, Shahnazari St, Madar Ave, Mirdamad,

City

Tehran

Postal code

Approval date

empty

Ethics committee reference number

159

Health conditions studied

1

Description of health condition studied

Rheumatoid Arthritis

ICD-10 code

M06.9

ICD-10 code description

Rheumatoid arthritis, unspecified

Primary outcomes

1

Description

Activity limitation

Timepoint

Baseline, 1 week and 1 month after rocker shoe Prescription

Method of measurement

Foot Function Index questioner

2

Description

Vertical ground reaction force

Timepoint

before, 1 week, 1 month after rocker shoe Prescription

Method of measurement

force plate

3

Description

Pain

Timepoint

Baseline, 1 week and 1 month after rocker shoe prescription

Method of measurement

Foot Function Index questionnaire

4

Description

Disability

Timepoint

Baseline, 1 week and 1 month after rocker shoe prescription

Method of measurement

Foot Function Index questioner

Secondary outcomes

empty

Intervention groups

1

Description

high top shoe with heel-to-toe rocker sole

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Firozgar hospital

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor for Research, Iran University of Medical Sciences
Full name of responsible person
Dr M. Moradi Lakeh
Street address
Iran University of Medical Sciences, Hemmat Expway
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice-chancellor for Research, Iran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Faculty of Rehabilitation, Iran University of Medical Sciences
Full name of responsible person
Dr Mohamad Sadegh Ghasemi
Position
Assistant Professor, PhD
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty