

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 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

###### Name

Mohamad Sadegh Ghasemi

###### Name of organization / entity

Iran University of Medical Science

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2222 9086

###### Email address

m.s.ghasemi@iums.ac.ir

#### 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 arthrodesism, 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****Street address**

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Faculty of Rehabilitation, Iran University of Medical University

**Full name of responsible person**

Masumeh Bagherzadeh cham

**Position**

Master of science in orthotics and prosthetics

**Other areas of specialty/work****Street address**

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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*