

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Designing and Developing of Forward Head Rounded Shoulder posture corrective Orthosis (FHRSO) and its Immediate Effect on Craniovertebral and Protraction-Retraktion angles in people with Postural deviations in upper body

#### Protocol summary

##### Study aim

Designing and Developing of Forward Head Rounded Shoulder posture corrective Orthosis (FHRSO) and its Immediate Effect on Craniovertebral and Protraction-Retraktion angles in people with Postural deviations in upper body

##### Design

A single group with repeated measure design. The participants randomly assigned to the sequence of with orthosis and without orthosis conditions.

##### Settings and conduct

The measurement was performed with the digital camera, that it was set at a distance of 1.5 meter, on a tripod, all assessments were conducted by a orthotics and prosthesis expert who did not participate in the invention of mentioned orthotics. Photo was recorded in the standing position in the lateral view. after the photography , data entered into the Digimizer software and the angles were evaluated.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age range 18 to 60 years old , and the angle of the craniovertebral less than 42/5 degrees.  
exclusion criteria: history of neck surgery, The history of neurological diseases, fractures in cervical vertebrae, scoliosis, rheumatic diseases, torticollis in neck, lack of balance in standing, neck pain, use of assistive device to hearing aids, congenital or bony abnormalities in neck vertebrae, systemic diseases such as arthritis, shoulder surgery history, history of any damage in the scapula and shoulder pain

##### Intervention groups

a single group with repeated measure design: with and without posture corrective orthosis

##### Main outcome variables

craniovertebral angle protraction-retraction angle

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200301046657N2**

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

Ali Khaghani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2222 0947

##### Email address

khaghani.a@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-01-21, 1398/11/01

##### Expected recruitment end date

2020-05-19, 1399/02/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Designing and Developing of Forward Head Rounded Shoulder posture corrective Orthosis (FHRSO) and its Immediate Effect on Craniovertebral and Protraction-Retractor angles in people with Postural deviations in upper body

### Public title

The effectiveness of corrective posture orthotics on head and neck

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

The age range of 18 to 60 years The angle of the craniovertebral is less than 42.5 degrees.

#### Exclusion criteria:

history of neck surgery The history of neurological diseases fractures in cervical vertebrae scoliosis rheumatic diseases torticollis in neck lack of balance in standing neck pain , use of assistive device to hearing aids congenital or bony abnormalities in neck vertebrae systemic diseases such as arthritis shoulder surgery history history of any damage in the scapula and shoulder pain

### Age

From **18 years** old to **60 years** old

### Gender

Male

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **30**

### Randomization (investigator's opinion)

N/A

### Randomization description

### Blinding (investigator's opinion)

Not blinded

### Blinding description

### Placebo

Not used

### Assignment

Other

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Iran University of Medical Sciences

##### Street address

School of Rehabilitation Sciences, Madadkaran All., Shahnazari St., Madar Sq., Mirdamad Blvd., Tehran

#### City

Tehran

#### Province

Tehran

#### Postal code

1545913487

#### Approval date

2020-01-03, 1398/10/13

#### Ethics committee reference number

IR.IUMS.REC.1398.1021

## Health conditions studied

### 1

#### Description of health condition studied

Forward head posture

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

protraction-retraction angle: the angle between the spinous process of C7 and the middle point of the humeral head and Horizontal line.

#### Timepoint

immediately effect

#### Method of measurement

The method of measuring the angles is photography with digital camera(Nikon D7000, Nikon Corporation, Japan) and method of calculating angles is with the Digimizer software( model 5.3.5 MedCalc Software )

### 2

#### Description

craniovertebral angle is the angle between ear Targus, the spinous process of C7 and the horizontal line.

#### Timepoint

immediately effect

#### Method of measurement

The method of measuring the angles is photography with digital camera(Nikon D7000, Nikon Corporation, Japan) and method of calculating angles is with the Digimizer software( model 5.3.5 MedCalc Software ).

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

In this study, using postural corrective orthosis, which is a assistive device to adopt the correct posture,

intervention is performed random with orthosis for 10 minutes, and the target angles are measured by phothography method.

**Category**

Treatment - Devices

**2****Description**

Intervention group: The target angles are measured by photography method random, without the use of postural corrective orthosis .

**Category**

Treatment - Devices

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Rehabilitation school of Iran University of Medical Sciences

**Full name of responsible person**

Reza Hamzelouei

**Street address**

Hashemi Alley-Shohada Square-Bonyad Blv

**City**

khomein

**Province**

Markazi

**Postal code**

3881917558

**Phone**

+98 86 4633 9228

**Email**

rezarh777@yahoo.com.sg

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Seyyed Abbas Motevalian

**Street address**

5th Floor, Iran University of Medical Sciences, next to Milad Tower, Hemmat Highway, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۴۳۹۶۱۴۵۳۵

**Phone**

+98 21 8670 2503

**Email**

research-m@iums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Iran 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**

Iran University of Medical Sciences

**Full name of responsible person**

Ali Khaghani

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Others

**Street address**

School of Rehabilitation Sciences of Iran University of Medical Sciences, Shahnazari St., Mother Square, Mirdamad Blv, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۳۴۸۷ - ۱۵۴۵۹

**Phone**

+98 21 2222 2059

**Email**

khaghaniali@yahoo.com

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

Iran University of Medical Sciences

**Full name of responsible person**

Ali Khaghani

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Others

**Street address**

School of Rehabilitation Sciences of Iran University of Medical Sciences, Shahnazari St., Mother Square,

Mirdamad Blv, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1545913487

**Phone**

+98 21 2222 2059

**Email**

khaghaniali@yahoo.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Reza Hamzelouei

**Position**

MSC student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Others

**Street address**

Bonyad Blv-Shohada Square-Hashemi Alley

**City**

Khomein

**Province**

Markazi

**Postal code**

3881917558

**Phone**

+98 86 4633 9228

**Email**

Rezarh777@yahoo.com.sg

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

Only the statistical information for variable-identifiable individuals is reported.

**When the data will become available and for how long**

Six months after printing results

**To whom data/document is available**

Supervisor in Study

**Under which criteria data/document could be used**

Do not publish identity information

**From where data/document is obtainable**

Rehabilitation school of Iran University of Medical sciences, Ali Khaghani

**What processes are involved for a request to access data/document**

After printing the article

**Comments**