

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Effects of Hydrotherapy versus Land Based Exercises on Pain and Grip Strength in Osteoarthritis of Hand

#### Protocol summary

##### Study aim

To find out the effects of hydrotherapy versus land based exercises on pain and grip strength in osteoarthritis of hand

##### Design

Parallel study groups, 68 sample size, phase 2, randomized, single center

##### Settings and conduct

Study setting is Aziz Bhatti Shaheed Hospital Gujrat, Pakistan. Participant will be allocated to the assigned treatment group after informed consent. Participant will not be aware of any other treatment given to other participant of same condition. Outcome assessor and data analyzer will be unaware of the treatment given to the participants.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: subjects between the age of 40-60 years old; criteria based on American College of Rheumatology. Exclusion criteria: patient with co morbidities; traumatic injuries of hand; hand surgery past 6 weeks; steroid injections past 2 weeks; cognitive or mental dysfunction.

##### Intervention groups

Group A: The participants will be treated with land based exercises and also treated with 5 minutes heat therapy as baseline treatment. Group B: The participants will be treated hydrotherapy based exercises and will be given 5 minutes heat therapy as baseline treatment

##### Main outcome variables

Pain and Grip strength

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200511047403N1**

Registration date: **2020-06-08, 1399/03/19**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-06-08, 1399/03/19**

Update count: **0**

##### Registration date

2020-06-08, 1399/03/19

##### Registrant information

###### Name

Zainab Naeem

###### Name of organization / entity

Riphah International University

###### Country

Pakistan

###### Phone

+92 53 7511911

###### Email address

noorzainab666@hotmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-06-01, 1399/03/12

##### Expected recruitment end date

2020-06-30, 1399/04/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effects of Hydrotherapy versus Land Based Exercises on Pain and Grip Strength in Osteoarthritis of Hand

##### Public title

Effects of Hydrotherapy versus Land Based Exercises on Pain and Grip Strength in Osteoarthritis of Hand

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

Subjects between the age of 40-60 years. Criteria based on American College of Rheumatology

**Exclusion criteria:**

Patient with co morbidities Traumatic injuries of hand  
Hand surgery past 6 weeks Steroid injections past 2 weeks Cognitive or mental dysfunction

**Age**

From **40 years** old to **60 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **68**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

After assessing the eligibility based on inclusion and exclusion criteria, the participants will be requested to take part in study with written as well as informed consent. The participants will be randomly allocated into either a water-based or land based exercise group by using lottery method. The participants will be assigned the group according to even or odd number drawn by the patient from the box. The participants drawing even number will be allocated to land-based exercise group and the participants with even number will be allocated to water-based exercise group.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Participant will be allocated to the assigned treatment group after informed consent. participant will not be aware of any other treatment given to other participant of same condition. Outcome assessor and data analyzer will be unaware of the treatment given to the participants.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Riphah College of Rehabilitation Sciences (RCRS)  
Research Ethical Committee (REC)

**Street address**

Near Hajj Complex, I-14, Islamabad, Islamabad  
Capital Territory

**City**

Islamabad

**Postal code**

46000

**Approval date**

2020-01-01, 1398/10/11

**Ethics committee reference number**

REC/RCRS/20/1011

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

Hand osteoarthritis, which is the most frequently occurring joint disease, commonly affecting first carpometacarpal joint, interphalangeal joints and distal and proximal interphalangeal joints (DIP and PIP). Functional limitations of hand osteoarthritis are pain, decreased hand strength and flexibility, and inhibition of activity and limitation of participation in functional tasks. Distorted physical appearance, lack of activity, and great loss of mastery may compromised the role of hand as well as self-identity

**ICD-10 code**

M19.9

**ICD-10 code description**

Arthrosis, unspecified

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

Pain

**Timepoint**

Before intervention and, 2 weeks, 6 months

**Method of measurement**

Numerical Pain Rating Scale

**2****Description**

Grip Strength

**Timepoint**

before intervention and, 2 weeks, 6 months

**Method of measurement**

Hand Held Dynamometer

**Secondary outcomes****1****Description**

Hand function

**Timepoint**

Before intervention and, 2 weeks, 6 months

**Method of measurement**

Functional Index for Hand Osteoarthritis (FIHOA)

## Intervention groups

### 1

#### Description

Intervention group 1: Water based Exercises (Hydrotherapy)

#### Category

Rehabilitation

### 2

#### Description

Intervention group 2: Land Based Exercises

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Aziz Bhatti Shaheed Hosptial

##### Full name of responsible person

Dr. Abdul Waheed

##### Street address

Bhimbar Rd, Mamada, Mahmada, Gujrat, Punjab

##### City

Gujrat

##### Postal code

50700

##### Phone

+92 53 9260104

##### Email

physiowaheed@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Abdullah Hospital

##### Full name of responsible person

Zainab Naeem

##### Street address

Railway Chowk, Karimpura, Lalamusa, Gujrat, Punjab

##### City

Lalamusa

##### Postal code

50200

##### Phone

+92 53 7511911

##### Email

zainitimi@gmail.com

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Abdullah Hospital

#### Proportion provided by this source

100

#### Public or private sector

Private

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

Other

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Abdullah Hospital

##### Full name of responsible person

Zainab Naeem

##### Position

Student

##### Latest degree

Bachelor

##### Other areas of specialty/work

Physiotherapy

##### Street address

Railway Chowk, Karimpura, Lalamusa, Gujrat, Punjab

##### City

Lalamusa

##### Province

Punjab

##### Postal code

50200

##### Phone

+92 53 7511911

##### Email

zainitimi@gmail.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Abdullah Hospital

##### Full name of responsible person

Zainab Naeem

##### Position

doctor

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Physiotherapy

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**Person responsible for updating data**

**Contact**

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Abdullah Hospital

**Full name of responsible person**

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doctor

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**Sharing plan**

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

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

there is no further information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not 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**

No - There is not a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available