

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effects of magnetotherapy and lumbar traction on the patients of sciatica

#### Protocol summary

##### Study aim

To determine the effectiveness of magnetotherapy and lumbar traction on sciatica patients.

##### Design

This is a double-blind, randomized, two phase study. subjects will be randomized to 2 different treatments in a cross-over design.

##### Settings and conduct

Johar medicare complex, lahore Green international University, Lahore Ali Fatima Hospital Lahore

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Low back pain of 3 months duration or longer present at least 5 out of 7 days a week Age between 28-80 at the start of the study Men and women of all ethnicities Signs and symptoms of lumbar radiculopathy. Willingness to refrain from making changes in non-study medications taken for sciatica Patients with failed back syndrome. Pain level of at least 4/10 on average on a scale of 0 to 10 for the past month Pain not attributable to malignancy, inflammatory arthritis such as rheumatoid arthritis, or infection by previous examinations or by laboratory testing Patients' agreement to keeping a log of their pain level and documentation of compliance with wearing of back device. Patients' agreement not to make changes in pain medication type of dosing during the study. Women of reproductive age agreeing to undergo a pregnancy test at baseline. Exclusion criteria: Patients with pacemakers Patients with mechanical heart pumps Pregnancy or breast feeding Presence of pain of greater intensity in any other location than the low back or the leg Presence of active cancer History of spinal infection Patients s/p spinal fusion with spinal rods over the lower lumbar spine

##### Intervention groups

group 1: magnetotherapy group 2: magnetotherapy with lumbar traction

##### Main outcome variables

reduction of pain and numbness in low back and leg

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210822052250N1**

Registration date: **2022-06-24, 1401/04/03**

Registration timing: **prospective**

Last update: **2022-06-24, 1401/04/03**

Update count: **0**

##### Registration date

2022-06-24, 1401/04/03

##### Registrant information

##### Name

Mohtishim Ahmed

##### Name of organization / entity

Riphah international university, Lahore

##### Country

Pakistan

##### Phone

+92 42 35035189

##### Email address

mohhtishim\_7@hotmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-08-01, 1401/05/10

##### Expected recruitment end date

2023-04-01, 1402/01/12

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effects of magnetotherapy and lumbar traction on the patients of sciatica

#### Public title

Effects of magnetotherapy and lumbar traction on the patients of sciatica

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Having mechanical neck pain more than three months and less than two years age between 25 and 60 years having normal laboratory test results absence of fracture, dislocation, tumor or infection on radiological investigation pain severity of at least 4/10 according to the visual analog scale (VAS) willingness to sign the informed consent form. Presence of disc bulge, protrusion or herniation at L4-L5, and L5-S1 level

##### Exclusion criteria:

pregnancy and breastfeeding having a cardiac pacemaker implanted metal implant or electronic device in any part of body a prior trauma (whiplash), surgical or algological intervention in lumbar area history or suspicion of any malignancy presence of inflammatory joint pain or diagnosis of a rheumatic disease presence of an open superficial wound presence of more severe pain in any part of body other than low back pain an advanced stage mood disorder, a neurological disorder (multiple sclerosis, syringomyelia, or Parkinson's disease) radiographical Grade  $\geq 2$  spondylolisthesis, spinal instability or advanced spondylarthrosis physical therapy for back pain within the last six months a history of drug use other than paracetamol (NSAIDs, centrally acting and narcotic analgesics) or discontinuation of such drugs less than three months before the enrolment.

#### Age

From **25 years** old to **60 years** old

#### Gender

Both

#### Phase

2-3

#### Groups that have been masked

- Participant
- Care provider
- Investigator

#### Sample size

Target sample size: **60**

More than 1 sample in each individual

Number of samples in each individual: **2**

the 1st treatment is provided on any selective day for that particular patient. the treatment session will be repeated after 3 days of the 1st session

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

60 patients have been selected by simple random sampling. participants names are drawn randomly from a pool where everyone has an even probability of being chosen. The participants are then asked to pick up the sealed opaque envelope on the basis of which participants are divided into 2 equal groups. The

participants who choose sealed envelope with Group A are placed in Group A and those choose Group B are placed in group B. both groups contain 30 participants each.

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

Assessment and treatment will be performed by two individuals. Assessor and analyzer of the data are those who are unaware of the grouping and will be unaware of which group each subject belongs to. The assessor is present only at the time of assessment (before and after treatment).

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

##### Ethics committee

###### Name of ethics committee

Research and ethics committee GIU

###### Street address

Green international university, 9km raiwind road, bhoptian chowk Lahore

###### City

Lahore

###### Postal code

Green international

##### Approval date

2022-02-15, 1400/11/26

##### Ethics committee reference number

R&EC/GIU/2254

### Health conditions studied

#### 1

##### Description of health condition studied

Sciatica

##### ICD-10 code

M54.3

##### ICD-10 code description

Sciatica

### Primary outcomes

#### 1

##### Description

Daily overall pain level

##### Timepoint

3 days

##### Method of measurement

scale of 0 to 10

## 2

### **Description**

pain in the low back

### **Timepoint**

3 days

### **Method of measurement**

0-10 pain scale

## 3

### **Description**

pain in the lower extremities

### **Timepoint**

3 days

### **Method of measurement**

0-10 pain scale

## **Secondary outcomes**

## 1

### **Description**

quality of life

### **Timepoint**

3 days

### **Method of measurement**

questionnaire: SF 36

## **Intervention groups**

## 1

### **Description**

Intervention group 1: In this group, patients with sciatica are exposed to regular soft tissue release, isometric exercises, stretching and Lumbar traction. these individuals are not exposed to magnetotherapy unit.

### **Category**

Treatment - Devices

## 2

### **Description**

Intervention group 2: In this group, patients with sciatica are exposed to regular soft tissue release, isometric exercises, stretching, Lumbar traction and magnetotherapy. these individuals are exposed to magnetotherapy unit which is a special modality based on biomagnetism. the upper pole is north while the lower pole is south. the field generate in north to south direction, pressing the disc bulge to the neutral position.

### **Category**

Treatment - Devices

## **Recruitment centers**

## 1

### **Recruitment center**

### **Name of recruitment center**

Johar medicare complex. lahore

### **Full name of responsible person**

Dr. Mohtishim Ahmed

### **Street address**

Johar medicare complex, 36-R, Shahalam Road, near Ayub chowk, Johar town, Lahore

### **City**

Lahore

### **Postal code**

54000

### **Phone**

+92 313 4414456

### **Email**

mohtishim.ahmed@giu.edu.pk

## **Sponsors / Funding sources**

## 1

### **Sponsor**

#### **Name of organization / entity**

Green international University

#### **Full name of responsible person**

Prof. Dr. Khaliq-ur-Rehman

#### **Street address**

green international university, 9km raiwind road, bhoptian chowk, lahore

#### **City**

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#### **Postal code**

54000

#### **Phone**

+92 322 4057371

#### **Email**

mohtishim.ahmed@giu.edu.pk

### **Grant name**

### **Grant code / Reference number**

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

Yes

### **Title of funding source**

Green international University

### **Proportion provided by this source**

10

### **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**

Academic

## **Person responsible for general inquiries**

### **Contact**

#### **Name of organization / entity**

Green international university, lahore

#### **Full name of responsible person**

Dr. Mohtishim Ahmed

**Position**

lecturer

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

**Street address**

Johar medicare complex, 36-R, Shahalam Road, near Ayub chowk, Johar town, Lahore

**City**

Lahore

**Province**

Punjab

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**Phone**

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mohtishimahmed77@gmail.com

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

Green international university, lahore

**Full name of responsible person**

Dr. Mohtishim Ahmed

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**Phone**

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**Email**

mohtishimahmed77@gmail.com

**Person responsible for updating data****Contact****Name of organization / entity**

Green international University, Lahore

**Full name of responsible person**

Dr. Mohtishim Ahmed

**Position****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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**

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**

Yes - There is 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

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

Effects of magnetotherapy and traction on the patients of sciatica

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

data will be available after publication for 2 months

**To whom data/document is available**

to the research committees only

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

copy right

**From where data/document is obtainable**

from the primary author only

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

simple email the primary author by mentioning the reason

**Comments**

no other information will be required