Clinical Trial Protocol
Iranian Registry of Clinical Trials
01 Nov 2022

EFFECTS OF GRASTON INSTRUMENT SOFT TISSUE MOBILIZATION IN PATIENTS WITH SCIATIC NERVE ENTRAPMENT

Protocol summary

Study aim
To determine the effect of graston instrument soft tissue mobilization in patients with sciatic nerve entrapment.

Design
Randomized Clinical Trial

Settings and conduct
Fatima Memorial Hospital Shadman Lahore.

Participants/Inclusion and exclusion criteria

Intervention groups
Group A: Participants will receive graston instrument soft tissue mobilization. Group B: Participants will receive combine treatment of graston instrument technique with lumbar traction and neural mobilization.

Main outcome variables
Numeric Pain Rating Scale (Pain) Modified Oswestry Disability Index (Functional Disability)
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Onset of radicular low back pain of less than 12 weeks.
Pain upon active SLR in 30-70°. Sensitivity: 0.67(11)
Specificity: 0.26 (12) Age group in range of 30-60 years.
Male only. Sciatic nerve entrapment diagnosed on MRI.

Exclusion criteria:
Spinal Fracture. Spinal tumor or any malignancy.
Rheumatologic disorders. Pain beyond 70° or below 30° on active SLR. Positive compression and distraction test of SI joint. Positive gaensien’s test Any red flags.

Age
From 30 years old to 60 years old

Gender
Male

Phase
N/A

Groups that have been masked
• Outcome assessor

Sample size
Target sample size: 18

Randomization (investigator's opinion)
Randomized

Randomization description
Patient will be recruited into Group A and Group B by lottery method (without replacement).

Blinding (investigator's opinion)
Single blinded

Blinding description
Single Blinded

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Riphah College of Rehabilitation and Allied Health Sciences

Street address
13-14-C-Civic centre , Near Hamdard Chowk,
Township Lahore

City
Lahore

Postal code
54000

Approval date
2019-07-29, 1398/05/07

Ethics committee reference number

Health conditions studied

1

Description of health condition studied
Sciatic Nerve Entrapment

ICD-10 code
M54.30

ICD-10 code description
Sciatica, unspecified side

Primary outcomes

1

Description
Pain

Timepoint
Treatment will be given to both groups for 4 weeks, 3 sessions per week and post treatment evaluation will be done after two weeks and follow up evaluation after one month by NPRS.

Method of measurement
Numeric Pain Rating Scale

2

Description
Functional Disability

Timepoint
Treatment will be given to both groups for 4 weeks, 3 sessions per week and post treatment evaluation will be done after two weeks and follow up evaluation after one month by MODI.

Method of measurement
Modified Oswestry Disability Index

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group A: Graston technique with help of graston instrument is applied (3 sessions per week for 4 weeks)

Category
Treatment - Other

2

Description
Intervention group B: Graston technique along with lumbar traction (Mechanical) and neural mobilization. (3 sessions per week for 4 weeks)

Category
Treatment - Other
Recruitment centers

1
Recruitment center
 Name of recruitment center
  Fatima Memorial Hospital Shadman Lahore
Full name of responsible person
  Dr Farhia Shah
Street address
  Shadman Rd, Ichhra Lahore, Punjab 54000
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  Lahore
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  +92 42 35940444
Email
  farhia@gmail.com

Sponsors / Funding sources

1
Sponsor
 Name of organization / entity
  Riphah International University QIE Campus
Full name of responsible person
  Dr Syed Shakeel ur Rehman
Street address
  13-14-C-Civic Centre, Near Hamdard Chowk, Township Lahore
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Fax
  shakil.urrehman@riphah.edu.pk
Email
  Grant name
  Grant code / Reference number
  Is the source of funding the same sponsor organization/entity?
  Yes
Title of funding source
  Riphah International University QIE Campus
Proportion provided by this source
  15
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
  Riphah International University QIE Campus
Full name of responsible person
  Muhammad Shahzad Qadree
Position
  Student
Latest degree
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Other areas of specialty/work
  Physiotherapy
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be 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
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