Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison between the effect of routine physiotherapy and routine physiotherapy with Psoas muscle direct myofascial release technique on pain and disability index in patient with chronic nonspecific low back pain

Protocol summary

Study aim

The aim of this study is to survey the effect of routine physiotherapy with Psoas muscle Myofascial release technique on pain and disability among patients with chronic nonspecific low back pain.

Design

Two arm parallel group randomized trial with control group, single blinded, phase 3 on 40 patients, random number table have been used for randomization

Settings and conduct

The subject of this study is the application of a kind of manual therapy that is being used in physiotherapy. The place of performing study is Isfahan Farhangian physiotherapy clinic. Intervention group receives routine physiotherapy and this manual technique (Psoas Myofascial release) and control group receives routine physiotherapy. The assessor is blinded and doesn't know what kind of treatment each participant has received.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Nonspecific chronic low back pain patient who have pain in lumbar for at least in past 3 months with tightness or stiffness of Psoas muscle. Non inclusion criteria: Serious spinal pathology and the conditions that result in non myofascial pain in lumbar region.

Intervention groups

Both intervention and control groups receive routine physiotherapy (consist of 20min electrotherapy, 5min Ultrasound, 10 min hot pack, exercise therapy). Intervention group will receive Psoas muscle Myofascial release technique in addition to routine physiotherapy. This technique is going to be done as following: In supine position with 90 degree hip and knees. Therapist puts her hands on Psoas muscle for 3 min and then will perform transvers sliding.

Main outcome variables

Pain score (on Visual Analog Scale); Disability index (Roland-Morris disability questionnaire)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201108049305N1**
Registration date: **2020-12-13, 1399/09/23**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-13, 1399/09/23**
Update count: **0**

Registration date

2020-12-13, 1399/09/23

Registrant information

Name

Kosar Iranpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3650 2472

Email address

k.iranpour75@rehab.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-20, 1399/08/30

Expected recruitment end date

2021-06-21, 1400/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison between the effect of routine physiotherapy and routine physiotherapy with Psoas muscle direct myofascial release technique on pain and disability index in patient with chronic nonspecific low back pain

Public title
Effect of Psoas myofascial release in nonspecific low back pain

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
18_60 years old patient with diagnosed nonspecific chronic low back pain Pain in lumbar region, at least since 3 months ago Score 3_7 in Visual Analog Scale Disability index score of 4_8 in Roland-Morris disability questionnaire Having enough literacy for filling the questionnaire Having at least two parameters of tree following conditions: - Positive modified Thomas test, at least in one side of pelvic - Tenderness due to pressure on Psoas muscle, at least in one side of pelvic - Producing pain and uncomfortable due to Psoas muscle maximum contraction, at least in one side of pelvic

Exclusion criteria:
Pregnancy BMI score more than 30 History of lumbar spine surgery Low back pain due to serious spinal pathology such as tumor, infection, inflammatory disorders Symptoms of disc herniation (reduction of lower extremity force, reduction of reflexes of lower extremity, positive Straight Leg Raise test in less than 45 degrees. No pain reduction in rest, No pain increasing with activity History of fracture in spinal region History of recent trauma to spine Pain in resting Joint disorders such as Rheumatoid Arthritis Lumbar vertebral Spondylolisthesis Using paregoric and muscle relaxant medicine in past 48 hours before assessment Fibromyalgia History of myofascial or rehabilitation treatment in past 2 months

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

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data and Safety Monitoring Board

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study simple randomization is used. For generating random sequence, table of random numbers generated by Start Trek website is used, there are 40 numbers in this table which are coding from 01 to 40. After writing the numbers by the researcher, she will read the randomized number from left to right, so the first 20 codes will be in the control group and the second 20 codes will be in the intervention group. Based on the time of attending, the participants will be coded from 01, 02, ..., 40 till the sample size being completed.

Blinding (investigator's opinion)
Single blinded

Blinding description
This is a single blinded study. The assessor (who going to assess the outcome measures and collect the data) will be blind. Each participant will be aware of treatment that is being used for her/him. The researcher(physiotherapist) is aware of each participant's sort of treatment. The person who prepares the article draft and Data Safety and Monitoring Committee, will not be aware of each participant's grouping.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences

Street address
Building No. 4, Isfahan University of Medical Sciences, Hezar Jarib Ave, Isfahan

City
Isfahan

Province
Isfehan

Postal code
81746-73461

Approval date
2020-09-26, 1399/07/05

Ethics committee reference number
IR.MUI.RESEARCH.REC.1399.386

Health conditions studied

1

Description of health condition studied
Nonspecific chronic low back pain

ICD-10 code
M54.5

ICD-10 code description
Low back pain

Primary outcomes

1

Description
Pain score
Timepoint
Before starting the treatment, 1day and 4 weeks after the end of treatment
Method of measurement
Visual Analog Scale

2

Description
Disability index
Timepoint
Before starting the treatment, 1day and 4 weeks after the end of treatment
Method of measurement
Roland-Morris Disability Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention is Psoas muscle myofascial release technique, This technique is going to be done as following: In supine position with 90 degree hip and knees. Therapist puts her hands on Psoas muscle for 3 min and then will perform transvers sliding. In the intervention group, in addition to this technique, routine physiotherapy is performed (consist of 20min electrotherapy, 5min Ultrasound, 10 min hot pack, exercise therapy). Patients will receive 8 sessions of routine physiotherapy in 3 weeks (3 sessions per week) and 4 sessions of myofascial release therapy (in sessions 1, 3, 5, 7).
Category
Rehabilitation

2

Description
Control group: Participants in the control group will receive routine physiotherapy in 8 sessions (consist of 20min electrotherapy, 5min Ultrasound, 10 min hot pack, exercise therapy).
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Isfahan Farhangian physiotherapy clinic
Full name of responsible person
Kosar Iranpour
Street address
In front of the General Department of Education of Isfahan Province, Hasht Behesht Blvd, Baghe Goldaste Ave, Isfahan city
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
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research@mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Kosar Iranpour
Position
Masters student
Latest degree
Bachelor
Other areas of specialty/work
Physiotherapy
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No. 12, Lale alley, Farabi 2 Ave, Ghadir Blvd, Sepahanshahr
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Person responsible for updating data

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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
Undecided - It is not yet known if there will be 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
Yes - There is a plan to make this available
Title and more details about the data/document
All data obtained, including information on the main outcomes and individual characteristics of the participants (including height, weight, body mass index and gender) will be published as an article without identifying the participant. If needed, individual information will be shared with other researchers and the Data Safety and Monitoring Committee.
When the data will become available and for how long
Access period starts 6 months after the results are published
To whom data/document is available
Researchers working in academic and scientific institutions can apply for information.
Under which criteria data/document could be used
Other researchers can be used to collect data or write systematic reviews, to guide and improve the quality of patients' treatment and encourage similar studies.
From where data/document is obtainable
Applicants should contact the general manager of this research to obtain documentation and data. For this purpose, contact Kosar Iranpour at 00989217104152, email address K.iranpour75@gmail.com and postal code 81799-37531. Address: No. 12, Lale Ally, Farabi2 Ave, Ghadir Blvd, Sepahanshahr Town, Isfahan.
What processes are involved for a request to access

data/document

After 6 months from the publication of the results of the study, individuals who have a certificate from academic institutions can apply for data and documents and receive the documents about 1 to 2 months later.

Comments