Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of corticosteroid injection & extra corporeal shock wave therapy efficacy in distal trigger point of quadratus lumborum muscle.

Protocol summary

Study aim
Comparison of corticosteroid injection & extra corporeal shock wave therapy efficacy on pain intensity, condition of lumbar functional , quality of life and threshold compressive pain in distal trigger point of quadratus lumborum muscle.

Design
This study is a randomized single-blind clinical trial in 54 participants with distal trigger point of quadratus lumborum muscle. Participants will be randomly assigned into tow groups to take extra corporeal shock wave and corticosteroid injection.

Settings and conduct
The target population are all patients with low back pain that has distal trigger point of quadratus lumborum muscle referred to the specialized clinics of Tabriz University of Medical Sciences. Sampling will be done by convenience randomized method. To conceal the allocation, the same envelope will be used in the opaque package to be numbered sequentially.

Participants/Inclusion and exclusion criteria
Inclusion criteria: existence lumbar pain more than 2 months; local tenderness and to have trigger point in quadratus lumborum muscle area; normal neurological examination; VAS score above 4. Exclusion criteria: any injection or physiotherapy in 3 months ago; dynamic spondylolisthesis in radiography.

Intervention groups
Participants will be randomly divided into tow groups (A and B). In group A patients will receive extra corporeal shock wave with 1500 shock whit low flux density 0.1 mj/mm2/min on trigger point in 5 sessions during 3 weeks and in group B injection triamcinolone (40mg) and lidocaiene 2% (2cc) (with syringe 5cc). Both groups will receive stretching exercises.

Main outcome variables
Pain intensity; condition of lumbar functional; quality of life and threshold compressive pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20100827004641N14**
Registration date: **2019-01-19, 1397/10/29**
Registration timing: **registered_while_recruiting**

Last update: **2019-01-19, 1397/10/29**
Update count: **0**

Registration date
2019-01-19, 1397/10/29

Registrant information

Name
Bina Eftekharsadat

Name of organization / entity
Tabriz university of medical sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-08-23, 1397/06/01

Expected recruitment end date
2019-03-20, 1397/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of corticosteroid injection & extra corporeal shock wave therapy efficacy in distal trigger point of quadratus lumborum muscle.

Public title
Comparison of corticosteroid injection & extra corporeal shock wave therapy efficacy on low back pain arising from quadratus lumborum muscle.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Existence lumbar pain more than 2 months Local tenderness and to have trigger point in quadratus lumborum muscle area Normal neurological examination VAS score above 4 Would like to participate in study No received of any drug simultaneously

Exclusion criteria:
Any injection or physiotherapy in 3 months ago Sacroiliac joint problem in examination Bertolleti”s syndrome Bleeding disorders Systemic infection and local infection in injection area Biography of allergic reaction to corticosteroid Pregnancy Dynamic spondylolisthesis in graphy Diabetes BMI 30 and above Patient discontent to treatment method.

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **54**
Actual sample size reached: **54**

Randomization (investigator's opinion)
Randomized

Randomization description
For random allocation of study participants to study groups, computer software Random Allocation Software (RAS) will be used through 4 and 8 glass block and allocation ratio of 1:1.

Blinding (investigator's opinion)
Single blinded

Blinding description
For concealment of the allocation, the same envelopes will be used in the opaque package to be numbered sequentially. Envelopes will be numbered from 1 to 100. The first envelope will be given to the first person who will be included in the study and will continue to complete the sampling.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Regional Ethics Committee of Tabriz University of Medical Sciences

Street address
Vice Chancellor for Research, Tabriz University of Medical Sciences, Golgasht St.

City
Tabriz

Province
East Azarbaijan

Postal code
5166614756

Approval date
2018-07-31, 1397/05/09

Ethics committee reference number
IR. TBZMED. REC. 1397.342

Health conditions studied

1

Description of health condition studied
Low back pain

ICD-10 code
M54.5

ICD-10 code description
Low back pain

Primary outcomes

1

Description
Quality of life

Timepoint
Evaluating the quality of life at the beginning of the study (before the intervention) and 2 and 4 weeks after the intervention.

Method of measurement
The Quality of Life Question SF-36

2

Description
Lumbar Fuctional

Timepoint
Evaluating the lumbar functional at the beginning of the study (before the intervention) and 2 and 4 weeks after the intervention.

Method of measurement
The Lumbar Functional Question Oswestry

3

Description
Threshold Compressive Pain
Timepoint
Evaluating the Threshold Compressive Pain at the beginning of the study (before the intervention) and 2 and 4 weeks after the intervention.
Method of measurement
Digital Algometer

4

Description
Pain Intencity
Timepoint
Evaluating the Pain Intensity at the beginning of the study (before the intervention) and 2 and 4 weeks after the intervention
Method of measurement
Ruler of VAS

Secondary outcomes

empty

Intervention groups

1

Description
patients will be received standard extracorporeal shock wave with 1500 shock wh low flux density 0.1 mj/mm2/min in 5 sessions during 3 weeks
Category
Treatment - Devices

2

Description
Triamcinolone (40mg) manufactured by Sinadaro's pharmaceutiical company and lidocaiene 2% (2cc) manufactured by caspin tamin's pharmaceutiical company (with sorang 5cc) will now be injected.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shohada hospital
Full name of responsible person
Negar Fasaie
Street address
Shohada hospital, Golshahr Ave., Elgoli
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Bina Eftekharsadat
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
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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