

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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)

Phone

+98 41 1330 3193

Email address

binasadat@tbzmed.ac.ir

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
Bertolletti'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 Functional

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 Intensity

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 pharmaceutical company and lidocaine 2% (2cc) manufactured by caspin tamin's pharmaceutical 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

Tabriz University of Medical Sciences

Full name of responsible person

Abolghasem Jooyban

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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

Physical Medicine

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Person responsible for scientific inquiries

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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