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Reflexogenic analgesic effect of trigger point injections in treatment of low back pain after degenerative lumbar spinal stenosis decompression surgery

Submission date
30/08/2024

Recruitment status
No longer recruiting

Registration date
25/10/2024

Overall study status
Ongoing

Last Edited
25/10/2024

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Pain, especially in the lower back, is one of the most common reasons for limited movement and disability in young people. Spinal stenosis, a condition where the spaces in the spine narrow and put pressure on the nerves, often requires surgery. However, even after surgery, many patients continue to experience pain for years. This study is exploring whether trigger point injections, which are commonly used to treat lower back pain, can help relieve pain and improve the quality of life for patients who still have pain after surgery for degenerative lumbar spinal stenosis.

Who can participate?
Adults over the age of 25 who have had successful surgery for spinal stenosis in the lower back can participate. To join the study, participants must have been experiencing ongoing back pain for more than three months that has not responded well to non-steroidal anti-inflammatory drugs (NSAIDs). There must also be no other known causes for their back pain.

What does the study involve?
Participants will receive trigger point injections, which are given into specific areas of muscle (intramuscular) or bone (intraosseous) that may be contributing to their back pain. The study will assess how effective these injections are in reducing pain and improving movement after surgery.

What are the possible benefits and risks of participating?
The possible benefits of participating include relief from pain, improved walking ability, reduced symptoms of intermittent claudication (pain in the legs from walking), and an overall improvement in quality of life. There are no known risks associated with participating in this study.

Where is the study run from?
Peoples' Friendship University of Russia

When is the study starting and how long is it expected to run for?
January 2021 to December 2025

Who is funding the study?
Medical Dental Institute in Moscow (Russia)

Who is the main contact?
The main contact for this study is Professor Al-Zamil Mustafa, mustafaalzamil33@gmail.com

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
3421

Study information

Scientific Title
Efficiency of lidocaine intramuscular and intraosseous trigger point injections in the treatment of residual chronic pain after degenerative lumbar spinal stenosis decompression surgery

Study objectives
The purpose of this study is to study the effectiveness of intramuscular and intraosseous lidocaine trigger point injections (LTPIs) in the treatment of residual lumbar pain after degenerative lumbar spinal stenosis (DLSS) decompression surgery and to compare the

analgesic and recovery effect of L4-S1 region and posterior superior iliac spine (PSIS) intramuscular and intraosseous LTPI after treatment and in the follow-up.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 05/12/2022, Ethics Committee of the Medical Dental Institute of Moscow (Miklukho-Maklaya 6, Moscow, 117198, Russian Federation; +7 (499) 936-87-87; support@rudn.ru), ref: 3216

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Medical and other records

Study type(s)
Quality of life, Efficacy

Participant information sheet

Health condition(s) or problem(s) studied
Degenerative lumbar spinal stenosis

Interventions
In our study we are going to study 2 groups. Control group and treatment group. The control group received only pharmacotherapy. The treatment group received lidocaine trigger point injection (LTPI) in addition to pharmacotherapy and consists of 4 subgroups.

1st subgroup: Intramuscular lidocaine trigger point injection in L4-S1
Trigger point injection in L4-S1 is a procedure for relieving pain and muscle tension in paravertebral trigger points by injecting 2%-4 ml of lidocaine. The procedure takes about 30 minutes, is performed on an outpatient basis and does not require special preparation from the patient. Using palpation, the most painful points are determined at the L4-S1 lev-el, which are most often located within 1-2.5 cm lateral to L4-L5 and L5-S intervals. In this area, an intramuscular needle can be inserted into the multifidus and erector spinae muscles. After treating the skin with antiseptic solution, the medication is administered, followed by the application of an aseptic dressing. Procedures were carried out 5 times with a time interval between procedures of 3 days.

2nd subgroup: Intramuscular lidocaine trigger point injection in PSIS
Trigger point injection in PSIS is a procedure for relieving pain and muscle tension in the PSIS projection by administering 2%-4 ml of lidocaine. The procedure takes about 30 minutes, is performed on an outpatient basis and does not require special preparation from the patient. Using palpation, the most painful points above the projection of the PSIS are determined. In this

zone, the muscle fibers of the multifidus spinal muscle (musculi multi-fidi), extending from the medial surface of the PSIS, muscle fibers of the gluteus maximus muscle, extending from the lateral-posterior surface of the PSIS are located [54]. It should be noted that according to our ultrasound observations and reports of other authors based on their cadaveric and MRI data, it was established that the origin of the gluteus maximus muscle extends to the medial surface of the PSIS and the sacral spinous processes. Moreover, in these studies, 81 ± 11% of the area between the midline and the PSIS was occupied by the gluteus maximus.
After treating the skin with antiseptic solution, the medication is administered, fol-lowed by the application of an aseptic dressing. Procedures were carried out 5 times with a time interval between procedures of 3 days.

3rd subgroup: Intraosseous lidocaine trigger point injection in spinous process L5 and S1
Intraosseous LTPI in spinous process of L5 or S1 is a highly effective analgesic procedure using intraosseous injection of an anesthetic into the spongy substance of L5 or S1 vertebra. The projection of the spinous process is determined by palpation. After treating the skin with an antiseptic solution, a needle with a mandrel is inserted with a screwing motion perpendicularly into the bone until the spongy substance is reached. Confirmation of the presence of a needle in the spongy substance is bone marrow aspiration. Approximately 2 ml of blood is mixed with medication and injected slowly. The procedure is followed by the application of an aseptic dressing. Procedures were carried out 5 times with a time interval between procedures of 3 days. In difficult cases (obesity, spinal deformity, keloid and hypertrophic Scars) intraosseous ultrasound guided injection was used.

4th subgroup: Intraosseous lidocaine trigger point injection in PSIS
Intraosseous LTPI in PSIS is a highly effective analgesic procedure using intraosseous injection of an anesthetic into the spongy substance of PSIS. The projection of the PSIS is determined by palpation. After treating the skin with an antiseptic solution, a needle with a mandrel is inserted with a screwing motion perpendicularly into the bone until the spongy substance is reached. Confirmation of the position of a needle in the spongy substance is bone marrow aspiration. Approximately 2 ml of blood is mixed with the drug mixture and injected slowly. The procedure is followed by the application of an aseptic dressing. Procedures were carried out 5 times with a time interval between procedures of 3 days. In difficult cases (obesity, spinal deformity, keloid and hypertrophic Scars) intraosseous ultra-sound guided injection was used.

Pharmacotherapy will be carried out for 2 weeks, injections into trigger points will be carried out 5 times every 2 days for 2 weeks. Clinical examination will be carried out before treatment and 7 days after treatment. The duration of the follow-up period was determined to be 6 months. Clinical examination of patients will be at the end of the 2nd month, 4th month and at the end of the 6th month.

Randomization process will be conducted by program software: Statistica Version: 12.0.1133.15 (x86/x64)

Intervention Type
Procedure/Surgery

Primary outcome measure
Before treatment, a week after treatment, after 2 months and 4 months of observation:
1. Pain assessment by visual analogue scale and Mc Gill Pain questionnaire
2. Assessment of impaired sensation: temperature, tactile and vibratory sensation by 5-point scale

3. Assessment of neurogenic claudication by Zurich Claudication Questionnaire (ZCQ)
4. Step activity monitoring by a pedometer
5. Motor deficit by 5-point scale
6. Electroneuromyography (ENMG):
6.1. Amplitude of Compound Muscle Action Potential (CMAP):
6.2. Terminal Latency
6.3. Conduction Velocity
6.4. Amplitude of Evoked Potential of Sural Nerves
6.5. F-wave and A-wave Abnormalities
7. MRI will measure the narrowing of the spinal canal at the L4-S1 level before and after decompression surgery and at the end of the follow-up period.

Secondary outcome measures
Before treatment, a week after treatment, after 2 months and 4 months of observation:
1. Quality of life by SF-36 questionnaire
2. Quality of enjoyment by Quality of Life Enjoyment and Satisfaction Questionnaire (Q-LES-Q-SF)
3. Assessment of sexuality disorders by the Sexual Function Evaluation Questionnaire (SFEQ)

Overall study start date
05/01/2021

Completion date
30/12/2025

Eligibility

Key inclusion criteria
1. European
2. Adult men and women from 25 to 60 years old
3. Residual pain syndrome is older than 6 months but less than 3 years after DLSS decompression surgery
4. Localization of the maximum pain syndrome in the lumbosacral joint
5. The severity of residual pain by visual analogue scale (VAS) is 6 scores and higher
6. DLSS decompression surgery was completed without complications and without significant negative dynamics according to magnetic resonance imaging (MRI) and electroneuromyography (ENMG) data
7. Signed voluntary informed consent to participate in this study

Participant type(s)
Patient, Population

Age group
Adult

Lower age limit
25 Years

Upper age limit
60 Years

Sex
Both

Target number of participants
224

Total final enrolment
99

Key exclusion criteria
1. Presence of allergic reactions to any of the drugs used
2. Severe cognitive disorders
3. Foraminal and lateral location of spinal canal stenosis and severe narrowing on MRI
4. Distal polyneuropathy of the peroneal and tibial nerves according to electroneuromyography
5. Ankylosing spondylitis
6. Rheumatoid diseases
7. Atherosclerotic peripheral arterial disease of the lower extremities
8. Muscular dystrophies of the lower extremities
9. Motor deficit
10. Bladder and bowel dysfunction
11. Diabetes mellitus
12. Pregnancy
13. Undergoing physiotherapy or acupuncture treatment

Date of first enrolment
01/04/2022

Date of final enrolment
20/06/2024

Locations

Countries of recruitment
Russian Federation

Study participating centre
Peoples' Friendship University of Russia
Miklucho-Maklaya 6
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Sponsor information

Organisation

Peoples' Friendship University of Russia

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Sponsor type
University/education

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ROR
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Funder(s)

Funder type
University/education

Funder Name
RUDN University

Alternative Name(s)
Российский университет дружбы народов, Rossiysky universitet druzhby narodov, Université RUDN, Universidad de Rusia de la Amistad de los Pueblos, , , Peoples' Friendship University of Russia

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Russian Federation

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
31/12/2026

Individual participant data (IPD) sharing plan
The datasets generated during and analysed during the current study will be stored in publicly available repository

IPD sharing plan summary
Stored in publicly available repository