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Timing of physical therapy after epidural steroid injection for low back pain

Submission date
10/12/2025

Recruitment status
No longer recruiting

Registration date
12/12/2025

Overall study status
Completed

Last Edited
12/12/2025

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
Low back pain and leg pain (sciatica) are very common health problems. Treatments often include medicines, physical therapy, and spinal injections (epidural steroid injections) to reduce inflammation and pain. However, it is not currently known what the best time is to start physical therapy after receiving a spinal injection. This study aims to find the optimal timing for physical therapy after a steroid injection. The goal is to determine if delaying physical therapy for 30 days allows the injection to work better and provides longer-lasting relief compared to starting it earlier or using medication alone.

Who can participate?
Adult patients (aged 18 years and over) with pain duration of at least 30 days, insufficient response to conventional medical treatments (NSAIDs, muscle relaxants) and/or prior physical therapy, and diagnoses of lumbar disc herniation (LDH), lumbar radiculopathy (LR), or axial discogenic low back pain confirmed by lumbar MRI.

What does the study involve?
The study involves three groups of patients:
A group receiving only standard medical treatment (painkillers and muscle relaxants).
A group receiving a spinal steroid injection and starting physical therapy 15 days later.
A group receiving a spinal steroid injection and starting physical therapy 30 days later.

The researchers assess the patients' pain levels and ability to perform daily activities over a 3-month period.

What are the possible benefits and risks of participating?
• Possible benefits: Participants may experience significant relief from low back and radicular leg pain, along with improved functional capacity in daily activities. The study also helps determine the optimal timing for starting physical therapy to ensure the longest-lasting pain relief.
• Possible risks: The injection procedure (TETSI) is minimally invasive. Potential minor side effects include temporary dizziness (vasovagal reaction), facial flushing, or temporary leg weakness (transient monoplegia), which typically resolve quickly without permanent issues. Serious complications are very rare.

Where is the study run from?
Kayseri State Hospital, Turkey.

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

Who is funding the study?
Abdulkerim GÖkoğlu Healthcare Ltd. Co., Turkey.

Who is the main contact?
Dr Abdulkerim Gökoğlu, akerimg@hotmail.com.

Contact information

Type(s)
Principal investigator

Contact name
Dr Abdulkerim Gökoğlu

ORCID ID
https://orcid.org/0000-0001-8071-4078

Contact details
İstiklal, Adana Çevre Yolu Cd. No:135/1
Konya
Türkiye
42020
+905326445608
akerimg@hotmail.com

Type(s)
Public, Scientific

Contact name
Dr Hüseyin Yiğit

ORCID ID
https://orcid.org/0000-0002-7739-9844

Contact details
Kavaklionu mah. Ali Baran Numanoglu cad. Urgup
Nevsehir
Türkiye
50400
+905313741235
huseyin.yigit@kapadokya.edu.tr

Additional identifiers

Study information

Scientific Title
Assessment of clinical efficacy of therapeutic epidural transforaminal steroid injection and timing of physical therapy applications

Acronym
TETSI-PTRA-Timing

Study objectives
The primary objective of this study is to evaluate the clinical efficacy of Therapeutic Epidural Transforaminal Steroid Injection (TETSI) in the management of low back pain and radicular pain. Specifically, the study aims to investigate the optimal timing for initiating Physical Therapy and Rehabilitation (PTRA) following the injection. It compares the therapeutic outcomes (pain reduction and functional improvement) between patients initiating PTRA on day 15 versus day 30 post-injection, against a control group receiving medical treatment alone.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 16/09/2021, Kayseri State Hospital Clinical Studies Ethics Committee (Kayseri State Hospital, Kayseri, 38010, Türkiye; +90352 336 88 84; gokogluak@erciyes.edu.tr), ref: 11535-703.01

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Low back pain, Lumbar radiculopathy, Lumbar disc herniation

Interventions

The method of randomization used in this study is a computer-generated randomization list to ensure allocation concealment.
Group 1 (Medical Treatment): Received oral pharmacological agents (NSAIDs, analgesics, muscle relaxants) based on clinical condition.
Group 2 (Early PTRA): Underwent Therapeutic Epidural Transforaminal Steroid Injection (TETSI) followed by Physical Therapy and Rehabilitation (PTRA) starting on day 15 post-injection.
Group 3 (Delayed PTRA): Underwent TETSI followed by PTRA starting on day 30 post-injection.
Intervention Details: TETSI used 40 mg/ml Methylprednisolone and 0.25% Levobupivacaine. PTRA consisted of a 2-week daily program including Hot Pack (20 min), Ultrasound (10 min), and TENS (20 min)

Intervention Type
Mixed

Primary outcome(s)
1. Pain intensity assessed measured using the Visual Analogue Scale (VAS), Numerical Rating Scale (NRS), Verbal Pain Intensity Scale (VPIS) and Faces Pain Scale (FPS) scores recorded by a blinded physician at baseline, day 15, and months 1 and 3

Key secondary outcome(s))

Completion date
30/03/2023

Eligibility

Key inclusion criteria
1. Pain duration of at least 30 days.
2. Insufficient response to conventional medical treatments (NSAIDs, muscle relaxants) and/or prior physical therapy.
3. Diagnoses of Lumbar Disc Herniation (LDH), Lumbar Radiculopathy (LR), or axial discogenic low back pain confirmed by lumbar MRI.
4. Patients without surgical indications or failed previous surgical interventions.

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
90 years

Sex
All

Total final enrolment
210

Key exclusion criteria
1. Diabetic and neuropathic pain.
2. Vascular atherosclerotic disease.
3. Rheumatism or inflammatory bowel disease.
4. Central nervous system disorders with a history of infarction.
5. Vitamin/mineral deficiencies, lymphedema, or history of thyroid/parathyroid iatrogenic hypocalcemia.
6. Missed appointments or irregular participation in the program.

Date of first enrolment
01/10/2021

Date of final enrolment
30/12/2022

Locations

Countries of recruitment
Türkiye

Sponsor information

Organisation
Kayseri Eğitim ve Araştırma Hastanesi

ROR
https://ror.org/02ysppy04

Funder(s)

Funder type

Funder Name
Abdulkerim GÖkoğlu Healthcare Ltd. Co.

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date