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Comparison between steroids taken by mouth and steroids administered by lumbar epidural for sciatica pain

Submission date
11/02/2021

Recruitment status
No longer recruiting

Registration date
24/03/2021

Overall study status
Completed

Last Edited
23/02/2021

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Sciatica refers to back pain caused by a problem with the sciatic nerve. This is a large nerve that runs from the lower back down the back of each leg. When something injures or puts pressure on the sciatic nerve, it can cause pain in the lower back that spreads to the hip, buttocks, and leg. The objective of the present study will be to compare the effectiveness of the medications of the systemic corticosteroids class in relation to lumbar infiltrations in the relief of sciatica caused by lumbar disc herniation.

Who can participate?
Patients with severe sciatica, with recent onset, being followed up at the Spine Surgery outpatient clinic at Hospital São Paulo and Hospital Municipal de Barueri

What does the study involve?
Patients will be drawn in two groups in relation to the treatment they will be submitted for pain relief and resumption of function. It is important to highlight that both treatments are routinely performed in this clinic and participation in the study does not increase the risk of therapy failure in resolving the clinical condition. In the first approach, an initial interview will be carried out and protocols filled out that seek to measure the intensity of the pain that the patient presents, as well as pertinent imaging exams will be requested if the patient does not have them. After 1 week of the initial care, the intervention will be performed, according to the group for which the patient was drawn. These correspond:
- Group 1: The participants of this group will be submitted to transforaminal epidural infiltration, with corticosteroids and analgesics of local action, performed in a surgical environment under sedation. In summary, the participant will be instructed to be admitted to the hospital on the same day of the procedure, fasting at least 8 hours. In the operating room, the participant will be in prone position (lying on his stomach) and, after medication to sedate and relieve the pain of the procedure, the researcher will perform the procedure, lasting about 20 minutes. After recovery from anesthesia, with about 3 hours, the participant will be discharged from hospital with the appropriate guidelines.
- Group 2: Participants in this group will undergo treatment with oral medications for 3 weeks,

these being 20mg prednisone, according to medical prescription.
After treatment, the participant will be reassessed in 3 weeks and 6 weeks after the intervention, in the same outpatient clinic where initial care was performed and, on this occasion, the pain and function forms will be reapplied in order to measure the improvement in pain and function obtained. with each treatment.

What are the possible benefits and risks of participating?
The main benefits of participating in the research include mainly the contribution to optimize the treatment of cases similar to yours, aiming at improving the indication of each one of them in the case of acute sciatica. For the participant, the main benefit is the relief of pain and improvement of the clinical condition and function, since both treatments are effective in resolving symptoms.
Each treatment modality has inherent risks, with low rates of probability of occurrence.

Where is the study run from?
1. Hospital São Paulo (Brazil)
2. Hospital Municipal de Barueri (Brazil)

When is the study starting and how long is it expected to run for?
September 2020 to July 2022

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Prof Marcel Tamaoki, marceltamaoki@gmail.com
Guilherme Porceban, gporceban@gmail.com
Renato Ueta, uetarenato@gmail.com

Contact information

Type(s)
Scientific

Contact name
Prof Marcel Tamaoki

ORCID ID
https://orcid.org/0000-0002-9539-4545

Contact details
St. Borges Lagoa, 786
Vila Clementino
São Paulo
Brazil
04038002
+55(11) 55797049
marcel.tamaoki@unifesp.br

Type(s)
Public

Contact name
Mr Guilherme Porceban

ORCID ID
https://orcid.org/0000-0002-5431-166X

Contact details
Av Onze de Junho, 1266. Apto 44
São Paulo
Brazil
04041004
+55(16)982007111
gporceban@gmail.com

Type(s)
Public

Contact name
Mr Renato Ueta

ORCID ID
https://orcid.org/0000-0002-3458-0184

Contact details
St. Borges Lagoa, 786
Vila Clementino
São Paulo
Brazil
04038002
+55(16)982007111
uetarenato@gmail.com

Additional identifiers

Protocol serial number
Ethics number: 4.460.808

Study information

Scientific Title
Lumbar transforaminal epidural injection versus systemic corticosteroids for the treatment of acute sciatica: a randomized clinical trial

Acronym
TEISC

Study objectives
Our hypothesis is that systemic administration of oral corticosteroids is equivalent to peri-radicular transforaminal infiltrations in relation to improvement of pain and function in patients

with higher intensity acute sciatica (Oswestry index greater than 40). Thus, if proven, the prescription of these medications may constitute a less invasive and more accessible option in the treatment of these patients. On the other hand, if the hypothesis is rejected, the systemic prescription of these medications can be reconsidered in view of the side effects associated with this medication class.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved in 14/12/2020, Research Ethis Committee of Federal University of São Paulo (Botucatu St., 740, 5 floor - CEP: 04023-900 - São Paulo-SP, Brazil; +55(11)5571-1062; no email provided), ref: 4.460.808

Primary study design
Interventional

Study design
Interventional randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Treatment for acute sciatica pain due to lumbar disc herniation

Interventions
This is a prospective randomized clinical trial developed at the Orthopedics-Column outpatient clinic of Hospital São Paulo (EPM / UNIFESP) and its affiliated Hospital Municipal de Barueri. Individuals with a clinical condition compatible with acute sciatica secondary to lumbar disc herniation are randomly allocated into 2 groups regarding the treatment of choice. The randomization is realized in the randomization module of RedCap database.
- Group 1: the participants of this group will be submitted to transforaminal lumbar epidural infiltration in the week following the initial care. Transforaminal epidural infiltrations are performed using aseptic technique in the operating room. After confirmation of the appropriate location in the foramen through fluoroscopy, 1 ml of iodinated contrast is injected to identify the emerging root. If the desired image is visualized, a solution containing 2.5 ml of analgesics with local action and 2.5 ml of particulate corticosteroids will be administered.
- Group 2: participants in this group will be treated with oral prednisone starting in the week following the initial treatment. The medication used is prednisone, a synthetic corticosteroid with low mineralocortocoid activity. The total dose accumulated in the treatment cycle is 650mg, capable of promoting anti-inflammatory effects without immunosuppression. In addition, this dose has a low risk of suppression of the hypothalamic-adrenal axis, considering that the total treatment time will not exceed 3 weeks.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Oswestry Disability Index measured at baseline, 21 days and 60 days.

Key secondary outcome(s)
1. Pain measured using visual analogue scale at baseline, 21 days and 60 days
2. Presence of neurological deficits - measurement of muscle strength (Global Strength Index, recommended by the Medical Research Council) and tactile sensitivity test compared to the contralateral side (as recommended in the sensitivity measurement protocols) at baseline, 21 days and 60 days

Completion date
01/07/2022

Eligibility

Key inclusion criteria
1. Age over 18 years and who accepted to participate in the research by signing the Informed Consent Form
2. Symptoms suggestive of acute sciatica such as low back pain radiating to the lower limbs respecting the specific limits of the lumbar dermatomes and physical examination showing signs of root irration to the tensioning maneuvers
3. Minimum duration of symptoms greater than 72 hours
4. Maximum duration of symptoms less than 4 weeks
5. Oswestry Disability Index with a score greater than 30 points
6. Imaging exams (radiographs and magnetic resonance) compatible with the clinical picture presented by the patients

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Key exclusion criteria
1. Refusal to sign the Informed Consent Form (ICF)
2. Patients who do not use medications and follow the guidelines of the research team
3. Patients with a clinical condition that requires immediate surgical intervention (for example, cauda equina syndrome)
4. Patients with a previous history of neoplasms or previous trauma (fractures or dislocations) in the spine
5. Patients with a previous history of spinal surgery
6. Patients with comorbidities that indicate chronic use of corticosteroids (autoimmune diseases, conditions of atopy) or that contraindicate the use of this medication class at any time (for example, type 2 diabetes mellitus, uncontrolled systemic arterial hypertension in the last month, pregnancy/puerperium, active peptic ulcer)
7. Previous history of allergy or intolerance to analgesics with local action and/or iodinated components used in TFEI

Date of first enrolment
15/12/2021

Date of final enrolment
31/12/2021

Locations

Countries of recruitment
Brazil

Study participating centre
Paulista Medical School - Federal University Of São Paulo
St. Botucatu, 740
Vila Clementino
São Paulo - SP
Brazil
04023062

Sponsor information

Organisation
Federal University of Sao Paulo

ROR
https://ror.org/02k5swt12

Funder(s)

Funder type
Other

Funder Name
Investigatior initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository (redcap.epm.br) and will be available upon request for the

authors. All the procedures and sociodemographic, clinical and procedures will be available for researchers who provide a methodologically sound proposal. The participant identification data are available only for the main author. In the initial interview, all the participants will be oriented about the sharing of his data and the agreement will be registered by the ICF. The dataset also will be publically available in the subsequent results publication.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes