

The use of hyaluronic acid in the treatment of abnormal narrowing of the spinal canal in the lumbar spine

Submission date 29/04/2022	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 16/05/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 17/04/2024	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Foraminal stenosis is the narrowing or tightening of the openings between the bones in the spine. These small openings are called the foramen. Foraminal stenosis is a specific type of spinal stenosis. Epidural administration of hyaluronic acid under ultrasound guidance followed by neuromobilization may hypothetically improve the sliding of the nerve sheaths in the tight space of the lateral recess and the intervertebral foramen, reducing the pain of the root type. The aim of this study is to assess pain after an epidural injection of hyaluronic acid with additional neuromobilization.

Who can participate?

Patients with pain complaints as a result of lumbar foraminal stenosis

What does the study involve?

The study involves the administration of a single dose of a hybrid form of hyaluronic acid called Sinovial HL, under ultrasound guidance, in the zone of expected compression of the nerve root from the intra-lamellar access. The Sinovial HL product (IBSA producer) is a very widely used preparation in osteoarthritis, but it is also registered for extra-articular administration (tendons, ligaments). After the injection, the patient is instructed on the method of neuromobilization in the spinal unloading position and will be asked to continue it throughout the observation period. Pain will be assessed before the intervention, after injection, and after neuromobilization.

What are the possible benefits and risks of participating?

Ultrasound-guided epidural injections are safe procedures but there may be complications such as infection at the injection site, and bleeding at the injection site, dural puncture, or nerve root. Improvement of the sliding (neurodynamics) of the nerve root within the radial recess under the influence of the action of hyaluronic acid with subsequent neuromobilization of the root may result in a reduction in pain and improved motor function of the limb.

Where is the study run from?

Sutherland Medical Center (Poland)

When is the study starting and how long is it expected to run for?
March 2022 to March 2023

Who is funding the study?
Sutherland Medical Center (Poland)

Who is the main contact?
Dr Piotr Godek
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Contact information

Type(s)

Principal investigator

Contact name

Dr Piotr Godek

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

The use of hyaluronic acid in the symptomatic treatment of foraminal stenosis of the lumbar spine

Acronym

HALFS

Study objectives

Lumbar foraminal stenosis is a very common form of lumbar degenerative spondylosis. It is a late consequence of damage to the intervertebral disc, which leads to secondary hypertrophy of the intervertebral joints. Epidural administration of hyaluronic acid under ultrasound guidance followed by neuromobilization may hypothetically improve the sliding of the nerve sheaths in the tight space of the lateral recess and the intervertebral foramen, contributing to the improvement of the nerve root trophic and, consequently, reducing the pain of the root type. The aim of the study is to assess pain after an epidural injection of hyaluronic acid with additional neuromobilization.

Principal hypothesis: Reduction of pain after epidural injection of hyaluronic acid with additional neuromobilization.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 27/04/2022, Institutional Review Board at Wroclaw Medical University (ul. Pasteura 1, 50-367 Wrocław, Poland; +48 (0)71 784 17 10; bioetyka@umed.wroc.pl), ref: KB-344/2022

Study design

Open-label prospective non-randomized controlled interventional clinical trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Patients with pain complaints as a result of lumbar foraminal stenosis

Interventions

The project involves the administration of a single dose of a hybrid form of hyaluronic acid called Sinovial HL, under ultrasound guidance, in the zone of expected compression of the nerve root from the intra-lamellar access. The Sinovial HL product (IBSA producer) is a very widely used preparation in osteoarthritis, but it is also registered for extra-articular administration (tendons, ligaments). After the injection, the patient is instructed on the method of neuromobilization in the spinal unloading position and will be asked to continue it throughout the observation period. Before the intervention, after injection, and after neuromobilization, the NRS pain scale (0-10), the Oswestry scale (0-50), the Roland-Morris scale (0-24), and the SLR test (measured in degrees of elevation to the first symptoms) will be used to assess pain.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Hyaluronic acid

Primary outcome(s)

1. Pain assessed using the Numerical Rating Scale (NRS, 1-10) at baseline and 1, 2, and 3 months after the intervention
2. Pain assessed using the Roland – Morris scale at baseline and 1, 2, and 3 months after the intervention
3. Pain assessed using the Straight Leg Raise Test (SLR test) at baseline and 1, 2, and 3 months after the intervention

Key secondary outcome(s)

Disability assessed using the Oswestry Low Back Pain Disability Questionnaire at baseline and 1, 2, and 3 months after the intervention

Completion date

01/03/2023

Eligibility**Key inclusion criteria**

1. Clinical symptoms of radicular pain in the lumbar region
2. MRI confirmed recital stenosis of degenerative origin
3. No other spine diseases (post-traumatic, systemic inflammatory diseases, cancer, birth defects)
4. Adults consenting to the injection
5. Mental contact ensuring cooperation in the period of neuromobilization

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Neurological deficit
2. The presence of other spine diseases (post-traumatic, systemic inflammatory diseases, neoplasms, birth defects)
3. Refusal to consent to the injection
4. Anticoagulants, other injection contraindications
5. Impeded contact with the patient, not promising cooperation during the period of neuromobilization

Date of first enrolment

01/06/2022

Date of final enrolment

31/01/2023

Locations

Countries of recruitment

Poland

Study participating centre

Sutherland Medical Center

Aleja Stanów Zjednoczonych 32/14

Warszawa

Poland

04-036

Sponsor information

Organisation

Sutherland Medical Center

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author Dr Piotr Godek (piotrgodek.smc@gmail.com) on reasonable request. Raw data (taking into account the anonymity of patients) will become available from the end of the study for 5 years. The research results will be passed on to other researchers in order to compare these results with the results of their own research.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		18/03/2023	17/04/2024	Yes	No