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# 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

**Registration date**
16/05/2022

**Overall study status**
Completed

**Last Edited**
17/04/2024

**Condition category**
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

# 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

## Primary study design
Interventional

## Study design
Open-label prospective non-randomized controlled interventional clinical trial

## 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
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# 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 |