ISRCTN14155217 https://doi.org/10.1186/ISRCTN14155217

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
piotrgodek.smc@gmail.com

Contact information

Type(s)
Principal Investigator

Contact name
Dr Piotr Godek

ORCID ID
http://orcid.org/0000-0001-7809-1289

Contact details
Aleja Stanów Zjednoczonych 32/14
Warszawa
Poland
04-036
+48 (0)506 817 838
piotrgodek.smc@gmail.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

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 measure
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

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

Overall study start date
01/03/2022

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

Age group
Adult

Sex
Both

Target number of participants
40

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

Sponsor details
Aleja Stanów Zjednoczonych 32/14
Warszawa
Poland
04-036
+48 (22) 673 60 43
klinika@smc.waw.pl

Sponsor type
Hospital/treatment centre

Website
https://www.smc.waw.pl/

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

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

Intention to publish date
20/05/2023

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