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Spinal manual therapy versus nerve root injection for patients with back-related leg pain

Submission date
25/02/2024

Recruitment status
Recruiting

Registration date
28/02/2024

Overall study status
Ongoing

Last Edited
21/01/2025

Condition category
Musculoskeletal Diseases

[X] 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
This study aims to investigate two common treatments for back-related leg pain—spinal manual therapy and cortisone injections—to understand the extent to which they improve pain, function, and quality of life in patients with sciatica. This is a randomised double-placebo controlled study. This means that participants are randomly assigned (like flipping a coin) to one of two treatment groups. One group gets active or real spinal manual therapy plus placebo (i.e., inactive) nerve root injection, and the other group gets active cortisone injection plus placebo spinal manual therapy. A strength of this approach is that both groups receive active or real treatment for back-related leg pain. The inclusion of a placebo in both treatment groups is also important. It strengthens the scientific approach and quality of the study.

Who can participate?
Adult patients aged at least 18 years old with back-related leg pain symptoms

What does the study involve?
Participants are treated for up to 12 weeks during the study. Up to 12 active or placebo spinal manual therapy treatments and up to 2 active or placebo nerve root injections are provided. Participants and their chiropractors decide on the number of consultations needed. Participants receive information on the management of back-related leg pain in a brief educational patient booklet, and simple strategies for remaining active and managing their pain. Participants also receive other supportive treatments during treatment visits—soft tissue (massage-like) techniques and heat or cold—if deemed appropriate based on their needs and shared decision-making with the treating chiropractor.

While participants receive treatments as part of the study, they can continue to see their family doctor and take painkillers as needed. Similarly, if they are receiving care from an alternative or complementary healthcare provider (e.g., physiotherapist, osteopath, massage therapist, acupuncturist)—they are asked to keep these therapies to a minimum while they receive the study treatments.

What are the possible benefits and risks of participating?
Spinal manual therapy and cortisone injections can help with back-related leg pain and may

directly benefit the typical symptoms. Treatments (up to 12 spinal manual therapy treatments and up to 2 nerve root injections) are provided at no cost during the 12-week treatment period. Participants in this scientific study may indirectly help future people with back-related leg pain. The two study interventions are safe and are part of standard current healthcare for back-related leg pain in Switzerland. Yet, a possible burden of the study is the time involved in receiving an active treatment and a placebo treatment. Based on the best available evidence, potential side effects associated with spinal manual therapy and cortisone injections are minor and short-lasting. For example, people who receive spinal manual therapy may experience mild muscle soreness, which typically resolves within 1 to 2 days. Some people experience minor side effects after cortisone injections such as increased pain at the injection site, pain in other areas, and lightheadedness.

Where is the study run from?
University Spine Centre Zurich at Balgrist University Hospital (Zurich, Switzerland)
Epidemiology, Biostatistics and Prevention Institute (EBPI) at the University of Zurich

When is the study starting and how long is it expected to run for?
June 2023 to July 2027

Who is funding the study?
The Swiss National Science Foundation (SNSF) and the European Centre for Chiropractic Research Excellence (ECCRE) are funding the study.

Who is the main contact?
PD Dr. Cesar Hincapié, DC PhD, cesar.hincapie@uzh.ch

Study website
https://www.ebpi.uzh.ch/en/translational_research/chronic_conditions_health/salubrity_randomized_clinical_trial.html

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Spinal manual therapy versus nerve root injection for the management of patients with lumbar radicular pain: the SALuBRITY randomised clinical trial

Acronym
SALuBRITY

Study objectives
SALuBRITY is a noninferiority trial. The null hypothesis is that spinal manual therapy (SMT) will be inferior to nerve root injection (NRI) in reducing leg pain impact at 12-weeks after randomisation in patients with lumbar radicular pain. The alternative hypothesis is that SMT will be noninferior to NRI in reducing leg pain impact at 12-weeks after randomisation in patients with lumbar radicular pain.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 12/03/2024, Kantonale Ethikkommission Zürich (Stampfenbachstrasse 121, Zürich, 8090, Switzerland; +41 43 259 79 70; info.kek@kek.zh.ch), ref: 2023-02217

Study design
52-week multicentre two-parallel-group assessor-blinded double-sham-controlled randomized noninferiority clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community, GP practice, Hospital, Other therapist office

Study type(s)
Quality of life, Treatment, Safety

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Lumbar radicular pain

Interventions
This study is a 52-week multicentre, two-parallel-group, assessor-blinded, double-sham-controlled, randomised noninferiority clinical trial with an embedded vanguard (internal pilot) phase, process evaluation, cost-effectiveness analysis, and an adjunct non-randomised patient preference cohort, to compare spinal manual therapy versus corticosteroid nerve root injection for the management of patients with lumbar radicular pain.

A central, web-based, stratified randomisation method is in the randomised controlled trial:
1. Active spinal manual therapy (SMT) plus sham-control nerve root injection (NRI).
Active SMT is a pragmatic therapeutic concept combining lumbar spine mobilisation and manipulation, as clinically indicated given patient presentation, clinician assessment, treatment tolerance, and shared decision-making between the patient and chiropractor. Sham-control NRI involves deep intramuscular dry needling without therapeutic intent, 2 cm proximal to the usual active periradicular injection location.
2. Active corticosteroid NRI plus sham-control SMT.
Active corticosteroid NRI involves periradicular injection of 1 ml of (4 mg) dexamethasone dihydrogenphosphate (non-particulate corticosteroid), with 1 ml of 0.2% ropivacaine. Sham-control SMT involves the application of manual manoeuvres mimicking spinal manual therapy without therapeutic intent; operationalised as the application of a high-velocity, low-amplitude thrust to the gluteal region, small oscillations of the lumbar spine flexion-distraction piece with contact on sacrum, and downward scapular thrusts, all without therapeutic intent.

Adjunct patient preference cohort (only for consenting participants that meet trial eligibility criteria but decline randomisation or participation in the RCT, with a strong preference for one of the active trial interventions or usual care):
3. Patient preference observational cohort arm interventions: a) active SMT; b) active corticosteroid NRI; c) usual care (i.e., any treatment recommended or offered by the healthcare professionals the patient would normally choose to see in the community).

Intervention Type
Procedure/Surgery

Primary outcome measure
Leg pain impact measured using the pain intensity, enjoyment of life, and general activity (PEG) scale (0 to 10) at baseline, 4, 8, 12, 26, and 52 weeks. The primary endpoint is leg pain impact assessed at 12 weeks after randomisation.

Secondary outcome measures
1. Overall back and leg pain impact is measured using the PEG scale at baseline, 4, 8, 12, 26, and 52 weeks.
2. Time to resolution of sciatica symptoms measured on a 6-point ordered categorical scale. Data will be collected by weekly SMS text messages for the first 3 months, then from months 4 to 12 the SMS data collection will change to monthly, or until patients report on two consecutive occasions that they have recovered.

3. Prognostic risk status as measured by the STarT Back (low/medium/high risk of poor outcome) at baseline, 12, 26, and 52 weeks.
4. Back pain disability/function as measured by the Oswestry Disability Index (ODI, 0 to 100) at baseline, 4, 8, 12, 26, and 52 weeks.
5. Sciatica symptoms as measured by the Sciatica Bothersomeness Index (SBI, 0 to 24) at baseline, 4, 8, 12, 26, and 52 weeks.
6. Sleep problems as measured by the Jenkins Sleep Scale (JSS-4, 0 to 20) at baseline, 4, 8, 12, 26, and 52 weeks.
7. Fear of movement as measured by the Tampa Scale for Kinesiophobia (TSK-11, 11 to 44) at baseline, 4, 8, 12, 26, and 52 weeks.
8. Pain catastrophizing as measured by the Pain Catastrophizing Scale (PCS-6, 0 to 24) at baseline, 4, 8, 12, 26, and 52 weeks.
9. Anxiety and depression as measured by the Hospital Anxiety and Depression Scale (HADS, 0 to 42) at baseline, 4, 8, 12, 26, and 52 weeks.
10. Pain self-efficacy as measured by the Pain Self-Efficacy Questionnaire (PSEQ-4, 4 to 24) at baseline, 4, 8, 12, 26, and 52 weeks.
11. Consultation-based reassurance as measured by the Consultation Reassurance Questionnaire (CRQ-12, 0 to 54) at baseline, 4, 8, and 12 weeks.
12. Therapeutic alliance as measured by the Working Alliance Inventory - short revised (WAI-SR, 12 to 60) at 4 weeks.
13. General health as measured by a self-rated general health item from the WHO 5-point ordinal scale at baseline, 4, 8, 12, 26, and 52 weeks.
14. Health-related quality of life as measured by the utility-based quality of life (EQ-5D-5L) at baseline, 4, 8, 12, 26, and 52 weeks.
15. Treatment expectations as measured by the Expectation for Treatment Scale (ETS, 5 to 20) at baseline.
16. Adverse events as measured by clinician reports and patient surveys at 4, 8, 12, 26, and 52 weeks.
17. Global perceived change as measured by the Patient Global Impression of Change (PGIC, 7-point) at 4, 8, 12, 26, and 52 weeks.
18. Patient satisfaction with care and with the results of care as measured by 5-point patient satisfaction scales at 4, 8, 12, 26, and 52 weeks.
19. Participant blinding success as measured by the Bang blinding index (BI) and James BI after first SMT and NRI intervention sessions and at 12 weeks.
20. Performance at work as measured by a single item (NRS, 0 to 10) at baseline, 4, 8, 12, 26, and 52 weeks.
21. Missed work as measured by capturing the number of days missed from work at baseline, 4, 8, 12, 26, and 52 weeks.
22. Healthcare utilisation as measured by capturing resource utilisation and medication use at baseline, 4, 8, 12, 26, and 52 weeks.

Overall study start date
01/06/2023

Completion date
31/07/2027

Eligibility

Key inclusion criteria

Current participant inclusion criteria as of 20/06/2024:
A patient will be eligible to participate in the trial if the following criteria are satisfied:
1. Aged 18 years of age and older
2. Consulting in general practice, telemedicine call centre, outpatient spine clinic, ED, or self-assesses with back or leg pain symptoms, and lumbosacral radicular pain or sciatica is suspected
3. At least moderate leg pain severity (≥3 out of 10 on NRS)
4. A lumbar spine MRI assessment available from the past 12 months
5. Following standard clinical assessment, the diagnosis of radicular pain caused by disc herniation (RAPIDH) is confirmed by a chiropractor - RAPIDH criteria score of ≥9 out of 20 (simplified weighted score of clinical signs and symptoms predicting RAPIDH: patient-reported unilateral leg pain [3 points], monoradicular leg pain [6 points], positive straight leg raise (SLR) ≤60° (SLR is positive if typical leg pain is produced between 0° and 60°) or positive femoral nerve stretch test [4 points], unilateral muscle weakness [3 points], unilateral ankle or patellar reflex decrease [4 points]; sensitivity 95%, specificity 71%)
6. Can read and communicate in German or English
7. An active email address and internet access via a mobile phone or computer

Previous participant inclusion criteria:
A patient is eligible to participate in the trial if the following criteria are satisfied:
1. Aged 18 years old and over
2. Consulting in general practice, telemedicine call centre, outpatient spine clinic, emergency department, or self-assesses with back or leg pain symptoms and lumbar radicular pain is suspected
3. At least moderate leg pain severity (≥3 out of 10 on NRS)
4. A lumbar spine MRI assessment available in the past 6 months
5. After a standard clinical assessment, the diagnosis of radicular pain caused by disc herniation (RAPIDH) is confirmed by a chiropractor - RAPIDH criteria score of ≥9 out of 20 (a simplified weighted score of clinical signs and symptoms predicting RAPIDH: unilateral patient-reported pain in legs [3 points], monoradicular leg pain [6 points], positive straight leg raise (SLR) ≤60° (SLR is positive if typical leg pain is produced between 0° and 60°) or positive femoral nerve stretch test [4 points], unilateral muscle weakness [3 points], unilateral ankle or patellar reflex decrease [4 points]; sensitivity 95%, specificity 71%)
6. Can read and communicate in German or English
7. An active email address and internet access via mobile phone or computer

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
99 Years

Sex
Both

Target number of participants

280 (randomised trial)

Key exclusion criteria
Current participant exclusion criteria as of 20/06/2024:
A patient will not be eligible to participate in the trial if any of the following criteria apply:
1. Suspected serious spinal pathology or ‘red flags’ (e.g., cauda equina syndrome, progressive or widespread neurological deficit, spinal cord compression, suspicion of malignancy, infection, fracture, inflammatory spondyloarthropathy)
2. A history of lumbar spine surgery
3. A history of corticosteroid injection for sciatica symptoms in the past 4 weeks
4. Currently receiving ongoing care from a chiropractor for the same problem
5. Serious comorbidity preventing them from attending a research clinic or being able to undergo assessments and interventions
6. Pregnant or breastfeeding, or suspicion of pregnancy
7. A contraindication for spinal manual therapy (congenital spine anomalies, spinal infection, spinal tumour, spinal fracture)
8. A contraindication for corticosteroid nerve root injection (allergy to contrast medium, severe diabetes, oral anticoagulation that cannot be paused)
9. Already taking part in another research study related to back and/or leg pain

Previous participant exclusion criteria:
A patient is not eligible to participate in the trial if any of the following criteria apply:
1. Suspected serious spinal pathology or ‘red flags’ (e.g., cauda equina syndrome, progressive or widespread neurological deficit, spinal cord compression, suspicion of malignancy, infection, fracture, inflammatory spondyloarthropathy)
2. A history of lumbar spine surgery
3. Currently receiving ongoing care from a chiropractor for the same problem
4. Serious comorbidity preventing them from attending a research clinic or being able to undergo assessments and interventions
5. Pregnancy or breastfeeding, or suspicion of pregnancy
6. A contraindication for spinal manual therapy (congenital spine anomalies, spinal infection, spinal tumour, spinal fracture)
7. A contraindication for corticosteroid nerve root injection (allergy to contrast medium, severe diabetes, oral anticoagulation that cannot be paused)
8. Is already taking part in another research study related to back and/or leg pain

Date of first enrolment
29/04/2024

Date of final enrolment
31/07/2026

Locations

Countries of recruitment
Switzerland

Study participating centre

Balgrist University Hospital – University Spine Centre Zurich (UWZH)
Forchstrasse 340
Zurich
Switzerland
8008

Study participating centre
University of Zurich – Epidemiology, Biostatistics and Prevention Institute (EBPI)
Hirschengraben 84
Zurich
Switzerland
8001

Sponsor information

Organisation
Universitätsklinik Balgrist

Sponsor details
Forchstrasse 340
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Switzerland
8008
+41 044 386 11 11
info@balgrist.ch

Sponsor type
Hospital/treatment centre

Website
https://www.balgrist.ch/

ROR
https://ror.org/02yzaka98

Funder(s)

Funder type
Not defined

Funder Name
Schweizerischer Nationalfonds zur Förderung der Wissenschaftlichen Forschung

Alternative Name(s)
Schweizerischer Nationalfonds, Swiss National Science Foundation, Fonds National Suisse de la Recherche Scientifique, Fondo Nazionale Svizzero per la Ricerca Scientifica, Fonds National Suisse, Fondo Nazionale Svizzero, Schweizerische Nationalfonds, SNF, SNSF, FNS

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Switzerland

Funder Name
European Centre for Chiropractic Research Excellence

Alternative Name(s)
Kiropraktorernes Videnscenter Syddansk Universitet, The European Centre for Chiropractic Research Excellence, ECCRE

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
Denmark

Results and Publications

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

Intention to publish date
01/03/2028

Individual participant data (IPD) sharing plan
The datasets generated and analysed during the current study will be available upon reasonable request from the Sponsor-Investigator. Requests should be emailed to cesar.hincapie@uzh.ch. An external data request process will be initiated and considered, when pertinent. Swiss law on health research (Human Research Act [HRA, RS 810.30]) and strict Swiss data protection laws apply.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	PPI project	17/01/2024	28/02/2024	Yes	No
Other publications	SALuBRITY blinding feasibility randomised controlled trial protocol	02/05/2024	04/06/2024	Yes	No
Other publications	Data from the blinding feasibility trial informing the blinding methods	14/01/2025	21/01/2025	Yes	No