Brief Title
Clinical Correlates of Pressure Pain Thresholds in Back and Leg Pain

NCT Number
NCT ID not yet assigned

Unique Protocol Id
Life2022-24

Record Summary | Protocol | Study Documents | Results

# Record Summary

Unrelease

Use this page to see the current status of a record in the PRS and find controls for managing the record. This page also has status information for the modules in the Protocol Section, along with links for editing those modules.

## Record Information

### Record Dates

| Last Updated | Initial Release | Last Release |
|---|---|---|
| 10/21/2024 13:43 | 10/21/2024 | 10/21/2024 |

### Status Details and Record Owner

| PRS Review | Public Site | Record Owner | FDAAA |
|---|---|---|---|
| Pending | Not yet registered | Robert A. Leach, DC, MS(c) (RLeach) | Non-ACT (Not Interventional) |

### Record Status

In Progress — Entry Completed — Approved — Released — PRS Review — Public

### System Validation and Review Dashboard

Protocol Validation | **Review Comments**

## 0 Major Issues

There are no major issues for this record.

## 0 Advisory Comments

There are no advisory comments for this record.

### General Record Comments

These include any comments about the overall record.

| Overall Record | Major | Advisory |
|---|---|---|
| General Comments > | 0 | 0 |

### Module-Specific Comments

These include comments about individual protocol modules.

| Protocol Module | Major | Advisory |
|---|---|---|
| Study Identification > | 0 | 0 |
| Study Status > | 0 | 0 |
| Sponsors and Collaborators > | 0 | 0 |
| Oversight > | 0 | 0 |
| Study Description > | 0 | 0 |
| Conditions > | 0 | 0 |
| Study Design > | 0 | 0 |
| Groups and Interventions > | 0 | 0 |
| Outcome Measures > | 0 | 0 |
| Eligibility > | 0 | 0 |
| Contacts and Locations > | 0 | 0 |
| IPD Sharing Statement > | 0 | 0 |
| References > | 0 | 0 |

**Record Event Dashboard**

**Review History (0)**

This page documents actions taken on the record after it is released for PRS Review.

Event | Tags | User/Reviewer | Date/Time

## No PRS Review History Recorded at This Time

Review history will appear once the record is released for review.

**Protocol Registration Preview**

This is a rough approximation of how the Protocol Registration will appear on the ClinicalTrials.gov public web site.

# Clinical Correlates of Pressure Pain Thresholds in Back and Leg Pain

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our disclaimer for details.

ClinicalTrials.gov Identifier: [Not yet assigned]

Recruitment Status: Completed
First Posted: *
Last Update Posted: *

* Date not available in PRS

**Sponsor:**

Leach Chiropractic Clinic

**Information provided by (Responsible Party):**

Robert A. Leach, DC, MS(c), Leach Chiropractic Clinic

## Study Description

Brief Summary:

Objectives: The purpose of this study was to determine whether tenderness and other commonly used chiropractic measures, when operationalized, improve after lumbar chiropractic manipulative therapy

after care.

| Condition or disease | Intervention/treatment |
|---|---|
| Segmental Dysfunction of the Lumbar Spine<br>Back Pain<br>Leg Pain | Chiropractic<br>Exercise<br>Cryotherapy<br>Device: Spinalator |

Detailed Description:

Across manual therapy professionals there is at present little agreement regarding how to quantitatively measure painful spinal lesions associated with uncomplicated back and/or leg pain.{Waddell, 1996 #564;Hegmann KT, 2019 #16740;Himelfarb I, 2020 #16733} In the United States, the Medicare program requires "pain and tenderness" reportage as a metric to diagnose spinal lesions (segmental dysfunction, or SDF) associated with uncomplicated back pain, prior to reimbursement of treatment by chiropractors. {Services, 2019 #16731} Medicare guidelines for chiropractors specifically list use of algometry as an acceptable way to record paraspinal tenderness.{CMS, 2019 #16198} However, research regarding paraspinal algometry to measure tenderness has to date yielded conflicting results.{Jung, 2023 #16196} Medicare suggests use of pain scales such as the Numeric Rating Scale (NRS) for reporting pain levels before, during, and after chiropractic care to determine when patients have achieved maximum improvement, are pain free, and therefore no longer eligible for reimbursement of spinal manipulation (SM), the primary component of chiropractic manipulative therapy (CMT).{CMS, 2019 #16198} While there is some prior research that correlates pain with paraspinal tenderness measured using algometry, there is no body of literature correlating these findings with other commonly used clinical variables required by Medicare for documentation, either before or after CMT.{Leach, 1993 #15773;Jung, 2023 #16196;Nim, 2022 #16201} For example, both Medicare and chiropractic practice guidelines advocate for clinicians to distinguish uncomplicated back pain associated with facet joint lesions (also considered SDF), from back and leg pain that may be caused by disc lesions. One of the clinical tests for this is a pain provocation measure known as the Kemp Test (or Kemp; the patient extends their trunk backwards and to the right or left, to see if back and/or leg pain are reported. Complaint of back pain only suggests "facet syndrome" while complaint of leg pain suggests "disc syndrome.").{CMS, 2019 #16198;Hawk, 2020 #16139;Editors, 2024 #16738} As presently used there is only weak clinical evidence for use of pain provocation tests such as Kemp Test, and we found no prior research comparing Kemp Test results with other outcome variables after CMT.{Editors, 2024 #16738} Among clinical variables validated by research, reported extensively in manual therapy literature, and advocated in the Medicare guidelines for documentation by chiropractors, aside from NRS pain scores, only use of self-reported measures such as the Oswestry Lower Back Pain Disability Questionnaire are fully validated and operationalized. {Fairbank, 2000 #16739;Hawk, 2020 #16139} Yet even this dependent variable has only rarely been correlated with paraspinal tenderness.{Leach, 1993 #15773} Only NRS pain and Oswestry measures have been used extensively in reportage of outcomes after CMT.{Clohesy NC, 2018 #16743;Hawk, 2020 #16139;Himelfarb I, 2020 #16733} Neither algometry nor the Kemp Test have been previously compared with Oswestry and NRS scores both before and after CMT, to determine whether these reported measures of SDF improve after chiropractic, or even whether they correlate with one another. This lack of research regarding promising and/or commonly used chiropractic dependent variables may factor into our inability to clinically define the Medicare diagnosis SDF, and may instead serve to perpetuate the "enigma of back pain."{Waddell, 1996 #564}

Differences between instruments and protocols used in clinical trials, performed only on pain free subjects, using only one or a few sessions of SM, and with small sample sizes may have contributed to prior conflicting reports regarding the ability of algometry to distinguish pain free from painful lower back muscles; also, studies conducted in university or controlled environments may lack generalizability to clinical practice.{Jung, 2023 #16196} When an examiner measures paraspinal tenderness by using an algometer asking the patient to say "yes" when discomfort is first noted, the corresponding value read from the instrument is termed the pressure pain threshold (PPT). Emerging evidence that the number

well.{Haas, 2004 #4710;Haas, 2014 #15996} For example, would SM twice a week for 4 weeks increase paraspinal PPTs and reduce PPT asymmetry (the difference between paraspinal tenderness on the right versus the left) more significantly than SM provided only once a week for 2 weeks? Extending the prior PPT work by reporting tenderness quantified by algometry along with other commonly reported and operationalized clinical measures, determining whether the variables improved as expected after care, and correlating the measures before and after chiropractic may help inform future prospective research of their validity with regard to measurement of SDF within the Medicare program.

## Study Design

| | |
|---|---|
| Study Type: | Observational |
| Actual Enrollment: | 98 participants |
| Observational Model: | Cohort |
| Time Perspective: | Retrospective |
| Official Title: | Clinical Correlates of Pressure Pain Thresholds in 98 Patients With Uncomplicated Back and Leg Pain: A Consecutive Case Series Chart Review |
| Actual Study Start Date: | January 1, 2018 |
| Actual Primary Completion Date: | October 9, 2023 |
| Actual Study Completion Date: | October 9, 2023 |

## Groups/Cohorts

| Group/Cohort | Intervention/treatment |
|---|---|
| Pressure Pain Thresholds in 98 Patients with Uncomplicated Back and Leg Pain<br><br>A computer search (EZ Biz software) for patients diagnosed with sciatica (i.e., ICD10 codes M54.31, M54.32, M54.41, and M54.42) or uncomplicated low back pain (ICD10 M54.4 or M54.50) identified 492 electronic charts. Of these 394 either failed to meet inclusion criteria (n = 62) or met exclusion criteria (n = 332) and were eliminated from the study, leaving pre-and post-treatment data from 98 new patients eligible for statistical reduction. Charts of patients seen consecutively who had been treated between January 1, 2018 and August 25, 2021 who met inclusion and exclusion criteria were included. | Chiropractic<br><br>SM used by the practitioner was the chiropractic side posture pisiform contact push move with a P-A thrust isolated to the lumbosacral joints and applied to the side of primary back and/or leg pain. Patients presenting with spondylolisthesis received a side posture distraction type maneuver instead of a P-A thrust. As pain began to subside during subsequent visits patients were transitioned to bilateral application of SM, rather than continuing treatment only on the side of back pain or radiculopathy.<br><br>Other Names:<br>• Spinal Manipulation<br><br>Exercise<br><br>Core spine stretch and strength training throughout the course of care.<br><br>Cryotherapy<br><br>Therefore, during each treatment session when patients reported pain they received |

reusable ice pack (Polar Ice, Pelton/Shepherd Industries, Stockton, California) wrapped in 2 layers of headrest paper, but otherwise applied directly to the skin vertically along the lumbosacral spine, for 5 minutes.

Device: Spinalator

When patients no longer reported leg pain, spinalator intersegmental traction at ~10 lb/F, while the patient was lying supine with an ice pack between the traction table and the lumbar spine, was permitted as a pretreatment to side posture lumbar manipulation.

Other Names:

- Intersegmental Traction

## Outcome Measures

Primary Outcome Measure:

1. Measurement of Pressure Pain Threshold and Paraspinal Asymmetry by algometry. [Time Frame: From enrollment to the end of treatment at 6 weeks.]

   The algometer used in this study was obtained from Wagner Instruments (Greenwich, CT, Model FPK 20) and we followed the Fischer{Fischer, 1986 #16187;Fischer, 1987 #16211} method of standardized application (1 kg/cm2/sec) of rate of force that was followed for all exams by the principal investigator, applied 3 cm bilateral to the L5 spinous (Figure 1). Reliability and validity studies for use of an earlier version of this same instrument have been published previously. {Fischer, 1987 #16211;Fischer, 1986 #16187;Waller R, 2015 #16748}

Secondary Outcome Measures:

1. Modified Oswestry Lower Back Pain Questionnaire [Time Frame: From enrollment to the end of treatment at 6 weeks.]

   The Oswestry Lower Back Pain Questionnaire is widely used in chiropractic, physical therapy and orthopedic practice and research with established reliability and validity,{Christensen, 2015 #16209} although the modification used by this practice is embedded within the software used by the clinic (E-Z Bis, Office ver. 13.1c) and has not been further tested.

2. NRS Lower Back and Leg Pain Scores [Time Frame: From enrollment to the end of treatment at 6 weeks.]

   The NRS used was a 0-10 scale in which patients self-rate their pain using whole numbers, where 0 is "no pain" and 10 is "unbearable pain". In this practice patients are asked to point to where they hurt, and the examiner records the site by marking it on a pain map placed in the patient's chart. Based on markings on the patient's pain map and verbal NRS pain scores, data collectors for this study applied these to the following pain site categories: L5/buttock right pain, L5/buttock Bilat pain (patient indicated pain across their lower back/buttock or in the midline), L5/buttock left pain, right leg pain, and left Leg pain. The NRS scale has known reliability and validity, is accepted for Medicare reportage, and is widely used throughout the profession.

3. Pain Provocation Operationalized Kemp Test [Time Frame: From enrollment to the end of treatment at 6 weeks.]

   Kato et al{Kato, 2024 #16212} may have been the first to report a modified Kemp test whereby it was positive if the maneuver provoked ipsilateral LBP, yet they still report the test as positive/negative without attaching a pain score to use of the maneuver. The practitioner in the present query had operationalized the Kemp test from a categorical measure to a continuous variable, by asking patients to rate their pain (0-10 NRS), and point to location of back pain: right/middle, left/middle, or across their lower back/buttock. Studies of reliability and validity of pain provocation tests in manual medicine are limited, and no single global metric nor even a group of tests have been established as a predictor for the presence of LBP. Certainly, this novel operationalization of the Kemp Test has not been reported elsewhere. Despite this limitation broadly speaking the use of lumbar range of motion to provoke pain (i.e., pain provocation tests) is recommended for evaluation of

## Eligibility Criteria

| | |
|---|---|
| Ages Eligible for Study: | 18 Years to 75 Years |
| Sexes Eligible for Study: | All |
| Gender Based: | No |
| Accepts Healthy Volunteers: | No |
| Sampling Method: | Probability Sample |

### Study Population

The setting was a rural practice with patients diagnosed with lower back and/or leg pain, typically seer by a solo chiropractic practitioner in Mississippi. Treatment included both manual diversified side posture chiropractic manual thrust procedures and pretreatment typically used in Mississippi including ice if back and leg pain, or ice plus SpinalatorTM if not obese and without leg pain (due to practitioner experience that SpinalatorTM may aggravate patients with leg pain and obese). Ancillary advice and counseling may not have been typical of other practices since the chiropractor also holds certification as a Master Certified Health Education Specialist; training included practicing a set of core exercise strength and stretch exercises and instruction to stay active, as well as advice regarding in home/at work use of 5 minutes of ice 5x per day followed by walking and stretching to tolerance.

### Criteria

Inclusion Criteria:

- Inclusion criteria included patients diagnosed with uncomplicated low back and/or unilateral leg pain regardless of severity or length of pain prior to presentation.

Exclusion Criteria:

- Exclusion criteria included: Patient with missing data on preliminary or follow up exam, initial OSWESTRY score <20%, initial NRS LS/leg pain score < 2/10, patient referred for exclusive car elsewhere, patient age <18 and >75, pregnancy, significant neurologic loss (more than numbness), MVA/litigation, patient with bilateral leg pain or diagnosis of central HNP, and patient seeing a staff doctor other than the principal investigator for this study.

## Contacts and Locations

**Locations**

**United States, Mississippi**

Leach Chiropractic Clinic, LLC

Starkville, Mississippi, United States, 39759

**Investigators**

| | | |
|---|---|---|
| Principal Investigator: | Robert Leach, DC, MS, RMCHES | Leach Chiropractic Clinic LLC |

## More Information

Other Resources:

Links provided by Robert A. Leach, DC, MS(c), Leach Chiropractic Clinic

abstract presentation

Publications:

Leach RA, Hayes K, Sullivan S. Correlates of Pressure Pain Thresholds in 98 Consecutive Patients with Uncomplicated Back and Leg Pain: A Retrospective Private Practice Cohort. Abstract presentation at the 2024 Association for Chiropractic Colleges Research Agenda Conference. March 23, 2024.

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|---|---|
| Responsible Party: | Robert A. Leach, DC, MS(c), Director, Leach Chiropractic Clinic |
| ClinicalTrials.gov Identifier: | |
| Other Study ID Numbers: | Life2022-24 |
| Last Verified: | October 2024 |

Individual Participant Data (IPD) Sharing Statement:

| | |
|---|---|
| Plan to Share IPD: | Yes |
| Plan Description: | De-identified individual participant data including primary and secondary outcomes collected on a spreadsheet will be shared upon request.<br><br>More information provided by Robert A. Leach, DC, MS(c), Leach Chiropractic Clinic |
| Supporting Materials: | |
| Time Frame: | De-identified individual participant data collected will be shared at 1 year after article publication for a period of 5 subsequent years. |
| Access Criteria: | IPD demographic and outcomes data will be made available upon request. |

Human Subjects Protection Review Board Status: Approved

Studies a U.S. FDA-regulated Drug Product: No

Studies a U.S. FDA-regulated Device Product: No