

A Single Dose of BRTX 100 for Patients With Chronic Lumbar Disc Disease (cLDD)

NCT04042844

Status	RECRUITING
Phase	Phase 2
Sponsor	BioRestorative Therapies
Enrollment	99 participants

Key Eligibility Criteria

Inclusion (22)

- A subject is eligible for inclusion if all the following criteria are met:
 - A high index of suspicion for discogenic pain, (i.e., painful degenerative disc(s) with or without protrusions less than or equal to 5 mm)
 - Chronic Lower Back Pain for at least 6 months
 - Pain commonly provoked by prolonged sitting, forward bending, lifting, twisting, coughing, sneezing, or Valsalva maneuvers
 - Failure of at least 6 months of conservative back pain care (can include any or all of the following: rest, anti-inflammatory medication, analgesics, narcotics, epidural injections or selective nerve root injections at the target level, facet joint injections, muscle relaxers, massage, acupuncture, chiropractic care)
- ... and 17 more (see full listing online)

Exclusion (42)

- A subject is not eligible to participate if any of the following criteria are met:
 - Spinal Deformity (Scoliosis greater than or equal to 20 degrees, spondylolysis, clinically or radiographically significant retrolisthesis or spondylolisthesis) detected on MRI or plain film radiographic assessment
 - Disc extrusions, sequestered fragments, facet cysts, or greater than moderate spinal stenosis on MRI.
 - Presence of a Grade V annular fissure observed within the index disc level during discography in a subject for whom provocation discography has been performed
 - Intervertebral disc with radiographic evidence of Modified Pfirrmann Grade 8 or greater
- ... and 37 more (see full listing online)

Locations (19 total)

Alabama Clinical Therapeutics, LLC, Birmingham, Alabama, United States
Source Healthcare, Santa Monica, California, United States
Boomerang Healthcare, Walnut Creek, California, United States
... and 16 more locations

<https://clinicaltrials.gov/study/NCT04042844>

DISCLAIMER: This document is for informational purposes only and does not constitute medical advice. Always consult your healthcare provider before enrolling in any clinical trial. Information may not be up to date — verify details at [ClinicalTrials.gov](https://clinicaltrials.gov). Generated by [ClinicalTrialsFinder.org](https://clinicaltrialsfinder.org).