

A Prospective Study to Evaluate the Efficacy of Iovera Lumbar Medial Branch Cryoneurolysis Versus Radiofrequency Ablation for the Treatment of Chronic Low Back Pain

NCT07214844

Status	RECRUITING
Phase	Not Applicable
Sponsor	Montefiore Medical Center
Enrollment	110 participants

Key Eligibility Criteria

Inclusion (8)

- Subjects at least 18 years of age at Screening
 - Primary complaint of axial low-back pain suggestive of bilateral facet joint involvement (i.e., facet mediated CLBP) by evidence of provocative testing (e.g., axial loading, paraspinal tenderness)
 - Low back pain is chronic (i.e., e 3 months' duration)
 - Low back pain is moderate to severe (score of e 5 to d 9) on the 0 to 10 NRS at Screening
 - Low back pain causes functional impairment (e 30% on ODI) at Screening
- ... and 3 more (see full listing online)

Exclusion (37)

- Active workers' compensation, personal injury, Social Security disability insurance (SSDI), or other litigation/compensation related to the spine
 - Serious spinal disorders (verified on magnetic resonance imaging (MRI)) that may impact outcomes, including any of the following:
 - Suspected cauda equina syndrome (e.g., bowel/bladder dysfunction)
 - Infection
 - Tumor
- ... and 32 more (see full listing online)

Locations (1 total)

Montefiore Multidisciplinary Pain Program, The Bronx, New York, United States