Chymopapain Chemonucleolysis re-introduction Study

Back ground

Chymodiactin, the previously available product used widely in Europe, North America and many other countries obtained FDA approval in 1982 and also MHRA approval, ceased to be available in 2002. Abbott Laboratories had recently bought Knoll Pharma, a subsidiary of BASF, who owned the rights to the product, to gain access to the D2E7 molecule, which became the drug Humira. However Abbot decided not to continue with Chymodiactin and it ceased to be available. DisCure Medical has been set up with plans to re-introduce Chymodiactin which still has FDA and MHRA approval. However due to the time lapse, some relatively minor changes in the manufacturing process are likely to necessitate a reintroduction by means of a clinical trial as proposed.

Study Design

The study is a single arm prospective study.

Patients with contained disc herniations at the L4-5 and L5-S1 levels will be randomized to injection of 1000 or 2000 pKat of Chymopapain.

Inclusion Criteria

A contained lumbar disc herniation at the L4-5 or L5-S1 level as determined by an MRI, and clinical symptoms corresponding to the location of the herniation.

VAS Leg pain of 50 mm or greater and the ODI exceeding 30.

Examination will have restriction of spinal movements and straight leg raising restricted to at least 45 degrees on the painful leg, with a positive bow string sign, with or without cross-over pain to the opposite leg.

They will have adequate non-operative treatment for 6 or more weeks which may include medication (NSAIDs and/or analgesics), physical therapy, or spinal injection (epidural or root block), will be between 20 and 65 years of age and have had no previous spinal surgical intervention.

Exclusion Criteria

Disc herniations at more than one level.

Disc herniation extruding through the posterior longitudinal ligament or sequestrated.

Spinal Injection within 3 weeks of informed consent. (epidural or root- block)

Previous spine surgery.

Cauda equina syndrome or a severe rapidly progressing neurologic deficit.

Lumbar spinal stenosis, spondylolisthesis, scoliosis, spinal tumor, spinal infection, ankylosing spondylitis.

Interested?

If you are interested in being involved in this study, please contact me ,

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