

About Clinical Research

Clinical research studies are designed to answer specific questions about study drugs and are needed to help find new and possibly better future treatments for diseases.

A study drug goes through several phases of clinical research to evaluate its safety and effectiveness. Depending on the results of the research, the study drug could later be available to the public.

Clinical research studies are performed in accordance with strict governmental guidelines. These guidelines help ensure that the study participant's safety and rights are protected during the clinical research study, while allowing valuable information about the study drug to be collected.

Volunteering to participate in a clinical research study is an important decision that should be thought through carefully. Participation is entirely voluntary and an individual has the right to decline participation or to discontinue participation at any time, for any reason, without penalty or loss of any of the benefits to which they would otherwise have been entitled.

Want To Know More?

If you would like more information about this clinical research study, please contact the number below. Contacting us does not mean that you will then be obliged to participate, nor is it certain that you will be suitable to participate.

Thank you. We hope to hear from you soon.

Clinic name:

Contact person:

Address:

Telephone:

Are you experiencing lower leg pain from a herniated disc?



If a herniated lumbar disc has resulted in lower leg pain, please consider joining this clinical research study.

Herniated Discs and Leg Pain

Your lower back is made up of five lumbar vertebrae (bones) which surround and protect your spinal cord. Nerves travel along your spinal cord, sending information back and forth from your brain to other parts of your body. In between the vertebrae are flat, flexible discs that act as shock absorbers when you walk, run or jump. These discs have a flexible outer ring and a soft gel-like center.

When a disc's gel-like center pushes through a weakened area of the disc it is called a herniated disc (or a slipped or ruptured disc). The gel may place pressure on the spinal cord or spinal nerves. This "pinches" the nerve and can lead to the leg pain associated with herniated discs. A herniated disc happens most often in the lower back and is one of the most common causes of lower back and leg pain.

About This Clinical Research Study

About 360 people in the United States will take part in this clinical research study. The active study drug is administered as an injection and is being compared with a control injection, (an injection that contains no medication). Three out of four participants will receive the active study drug.

Current Treatments

Common treatments for herniated discs include:

- Medications such as:
 - Pain relievers (acetaminophen and ibuprofen)
 - Narcotics (Vicodin, Lortab)
 - Nerve pain medications (Neurontin, Lyrica, Cymbalta, tramadol, amitriptyline)
 - Muscle relaxants (Valium, Flexeril, Amrix)
- Cortisone injections
- Physical therapy
- Surgery

Who Can Take Part?

You may be eligible to participate if you:

- Are experiencing lower leg pain associated with lumbar disc herniation
- Are 30 to 70 years of age
- Are Not on worker's compensation

There are also other study requirements that will determine if you qualify. With your permission, these criteria will be reviewed by the study doctors and nurses when you contact or visit the research center listed on the back of this brochure.

What Will Study Participants be Asked to Do?

The first step will be to meet with a member of the study team at your local research center to review an Informed Consent Form. This form fully explains the purpose of the study, possible risks and benefits and what will be expected of you as a participant. No procedures will begin until you have had all your questions answered and have signed this form signifying your understanding of its contents and your agreement to take part.

Participants in this clinical research study will receive one injection of the study drug (or a control injection). Involvement in the study will be about 26 months, during which participants will be asked to attend up to 12 study visits. All of the study visits will occur at the research center.

Throughout the study, staff will monitor your health. They will perform physical examinations and collect blood and urine samples for laboratory testing. Participants will also receive an MRI and X-Ray. You will also be asked questions about leg-pain, medications being taken, and any side effects that you might have experienced.