

Rush University Medical Center seeks participants for the NeoCart Clinical Trial

A Randomized Comparison of NeoCart to Microfracture for the Repair of Articular Cartilage Injuries in the Knee – Phase III / Confirmatory Study



Rush University Medical Center is participating in a research study evaluating an investigational treatment called NeoCart®, a tissue implant made from a patient's own cells, aimed at repairing certain knee cartilage injuries. The study will look at damage to the knee's hyaline articular cartilage, the smooth, white tissue that covers the ends of bones where they come together to form joints. Damage to this cartilage may be caused by an injury or repetitive motion. It is a common problem that results in pain and symptoms, such as swelling, locking of the knee and loss of knee function. Damaged hyaline cartilage has limited capacity to repair or restore itself. Left untreated, the damage may progressively worsen and may lead to chronic conditions such as osteoarthritis.

The purpose of this company-sponsored Phase 3 study is to learn about the safety and potential efficacy of the investigational cartilage tissue implant, NeoCart®, compared to microfracture, the current standard of care surgery for articular cartilage defects of the knee. A total of 245 patients will participate in the NeoCart Clinical Trial in up to 40 sites across the United States.

Criteria

Patients who are between 18 and 59 years old and who have symptoms of pain in one knee may be candidates for this study. However, those who have previously failed other treatments or smoke more than one pack of cigarettes per week may not be eligible.

Patients accepted into the study will have a two out of three chance of being treated with NeoCart® and a one out of three chance of receiving the microfracture procedure. Patients in each group will have a specific rehabilitation plan and will be evaluated periodically for three years after treatment.

Any patient who meets all of the following criteria may be included into this study. The patient must be:

- Able and willing to give informed consent.
- 18 years to 59 years of age.

- Symptomatic with knee pain indicative of an articular cartilage injury of the distal femur and/or trochlea. Baseline KOOS pain score must be <80 and baseline IKDC Subjective score must be <70.
- Medically able to undergo arthroscopy, arthrotomy for NeoCart® implantation, and serial MRIs.
- Females must be post-menopausal or practicing an acceptable form of birth control.

The study sponsor is Histogenics, Corp. For more information, text knee1 to 87888, call (773) 257-7057 or visit www.NeoCartImplant.com.

Caution: New Biologic. Limited by federal law to investigational use only and is not available for sale.