

Researchers studying stem cell therapy to repair damaged knee cartilage

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Rush University Medical Center is conducting the nation's first clinical study of an innovative stem cell drug, Cartistem, to repair knee cartilage damaged by aging, trauma or degenerative diseases such as osteoarthritis.

Cartistem is manufactured from <u>mesenchymal stem cells</u> derived from allogeneic (donor) umbilical cord blood. Umbilical cord blood is a readily accessible source of high-quality stem cells, is associated with minimal health risks and carries relatively few ethical concerns.

The stem cells are mixed with <u>hyaluronan</u>, a <u>natural polymer</u> that plays a major role in wound healing and is a building block of <u>joint cartilage</u>. Cartistem is surgically administered into the area of cartilage damage following an arthroscopic surgery as an adjunct to microfracture, a commonly used technique used to repair cartilage damage.

The principal investigator on the study is Dr. Brian Cole, a professor in the department of orthopedics and anatomy and cell biology at Rush University Medical Center. Dr. Cole is the head of Rush's Cartilage Restoration Center and is also the head team physician for the Chicago Bulls. Cole and his co-researchers will assess the drug's safety as well as its ability to regenerate <u>cartilage repair</u> tissue and reduce pain in patients with localized cartilage loss in the knee.

Treating cartilage damage can be problematic because the tissue does not contain blood vessels or nerves and therefore has a limited ability to re-



grow. Various treatments for cartilage degeneration, such as drug therapy, arthroscopy and joint replacement, yield mixed results and are unable to regenerate damaged tissue.

"Finding a biological solution for cartilage regeneration in orthopedics is one of the fastest growing areas of research and development in our specialty, said Cole. "Rush is spearheading this field of research with the ultimate goal of safely improving outcomes and sparing patients from having more complicated surgery at a relatively young age."

The two-year, phase I/IIa study will enroll a total of 12 participants aged 18 years and older, with a body mass index of less than 35. Initially, six individuals with lesions sized 2 to 5 centimeters will be recruited into the study; an additional six volunteers with lesions larger than 5 centimeters will be enrolled sequentially. Each participant will undergo eligibility screening followed by a 12-month observation period to determine the safety and efficacy of the drug with an additional long-term follow-up evaluation at 24 months.

"With a burgeoning aging, yet active population, our patients are looking for effective non-joint replacement solutions to treat their damaged <u>knee</u> <u>cartilage</u>," said Cole. "This research is significant in that it utilizes a commonly performed operation (microfracture) in an effort to improve upon variable outcomes."

"Notably, this is a treatment for patients with localized <u>cartilage damage</u> and not for patients who are diagnosed with diffuse or bone on bone arthritis who have otherwise been told they require a knee replacement." said Cole.

Provided by Rush University Medical Center



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