

A CLINICAL RESEARCH STUDY FOR ADULTS WITH ARTICULAR CARTILAGE INJURY OF THE KNEE.

Purpose

The primary purpose of this study is to evaluate the safety and effectiveness of HYALOFAST® scaffold with bone marrow aspirate concentrate (BMAC) in the treatment of articular cartilage defect lesions.

HYALOFAST is a hyaluronan-based scaffold that is used together with autologous BMAC in a one-step procedure to treat symptomatic cartilage defects of the medial and/or lateral femoral condyle or the femoral trochlea.

Design

This is a prospective, randomized, active-treatment-controlled, evaluator-blinded (radiologist reviewer and physician evaluator), multicenter study. The study is designed to establish the superiority of a hyaluronan-based scaffold (HYALOFAST) with autologous bone marrow aspirate concentrate in the treatment of articular knee cartilage defects in comparison to the control, called microfracture treatment. HYALOFAST is not approved for use in the United States; however, it is approved in Europe and has been in use since 2009.

Subjects who are eligible for the study after screening will be randomized (1:1) between the two arms, which are either HYALOFAST with BMAC treatment or microfracture treatment. All subjects will be assessed at intervals to measure effectiveness post-procedure at 1 month, 3 months, 6 months, 12 months, 24 months, and 36 months. The primary effectiveness endpoint assessments are done at the 24-month time point. Evaluators doing efficacy assessments of the subject and administering subject-reported outcome instruments will be blinded to the treatment.

Main qualifying criteria

In addition to other inclusion criteria, each subject must meet all of the following criteria to be qualified to participate in this study:

1. Patient is male or female between 18 and 60 years of age.
2. Patient's body mass index (BMI) is < 35 kg/m²
3. Patient has a symptomatic lesion of the femoral condyle (medial and/or lateral) or the femoral trochlea that is between 1 and 6 cm² on screening images confirmed by the independent radiologist.
4. The symptomatic lesion is classified as International Cartilage Repair Society (ICRS) grade 3 or 4.

(continued on back)



5. Patient agrees to actively participate in a strict rehabilitation protocol and follow-up program.
6. Patient is using only nonsteroidal anti-inflammatory drugs (NSAIDs) or acetaminophen/paracetamol during the month before signing the informed consent form to treat knee pain.

Main exclusion criteria

In addition to other exclusion criteria, a subject will not be eligible for study participation if he or she meets any of the following criteria:

1. Major concomitant cartilage lesions that require extensive surgical treatment. Lesions such as minor loose bodies, small debris fragments, small cartilage fragments, or prominent knee fat pad are allowed. These lesions may be treated with debridement.
2. Presence of a kissing (bipolar) lesion that is opposed to the index lesion and is deeper than grade 2 (ICRS classification), as determined by MRI. Presence of a kissing (bipolar) lesion that is opposed to the index lesion, deeper than grade 2, and discovered under arthroscopy is allowed. The non-index lesion, if indicated for treatment, should be treated with the study-assigned treatment of the index lesion.
3. Diagnosed advanced osteoarthritis as demonstrated by a Kellgren-Lawrence grade of 3 or 4 in the index knee.
4. Complex ligamentous instability of the index or contralateral knee. Previous reconstructions of ACL or PCL are allowed – of either the index or contralateral knee – if instability is not present. Grade 1 ligamentous injuries are allowed.
5. Infections or skin diseases at target knee joint.
6. Diagnosed osteochondritis dissecans (OCD).

Thank you

We appreciate your interest in the FastTRACK Study. If you know someone who may be eligible, please refer him or her to the participating study doctor listed below and to [FastTRACKStudy.com](https://www.fasttrackstudy.com) to learn more.

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