

# The Success of JointStem Phase 3 Clinical Trial, World's First Stem Cell Treatment for Osteoarthritis of the Knee

*The successful outcome of stem cell research and development for reduction of pain and improvement of knee cartilage function in patients with severe OA*

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- Successful data for the reduction of pain and the improvement of knee cartilage function in severe osteoarthritis (OA) patients with Kellgren and Lawrence (K-L) grade 3
- The outcome of Korean stem cell research and development of 16 years and the results of hard work including tens of millions of dollars in investment
- A new era for a new therapy that does not require surgery- only one injection into the joint cavity to help cure osteoarthritis

Nature Cell announced on May 17, 2021 that the phase 3 clinical trial of JointStem, the world's first stem cell treatment for severe knee osteoarthritis using autologous adipose tissue-derived mesenchymal stem cells (AdMSC), has been successful in Korea. JointStem is developed by RBio, an affiliate of Nature Cell.

Nature Cell received the clinical study report (CSR) on May 14, 2021 from LSK Global PS, the contract research organization (CRO), and the CSR confirmed that the efficacy and safety of JointStem for pain reduction and knee cartilage function improvement in patients with K-L grade 3 severe knee osteoarthritis was statistically significant.

JointStem has been developed from 2005 with original Korean bio technologies. Tens of millions of dollars have been invested for the development. We believe JointStem will open a new era for the treatment of arthritis just in one injection, which is different from other existing treatments requiring surgery.

According to the CSR, WOMAC (Osteoarthritis Index) and VAS (Pain Index), the primary evaluation variables of the clinical study improved from the baseline scores before the injection to higher scores after 24 weeks of the injection, in terms of the score changes larger than those of placebo injection, which is statistically significant; The study found statistically significant improvements in the two evaluation variables when the JointStem injection group was compared to the placebo injection group ( $p=0.0002$  and  $p<0.0001$  for each corresponding variable). Generally, it is considered successful in a statistical analysis if the p value is less than 0.05, however, it is

considered as failed to achieve a statistical significance if the p value is over 0.05. Two evaluation variables scored significantly lower values than the standard value.

Other secondary evaluation variables are the WOMAC subgroup (pain, stiffness, and difficulty in performing daily life evaluations), KOOS evaluation (Knee Injury and Osteoarthritis Outcome Score) and SF-36 (Quality of life evaluation), X-rays, MRI, and the dosage and number of days of pain relief medicine usage were also evaluated. All the evaluation scores of WOMAC subgroup (pain, stiffness, and difficulty in performing daily life) decreased to the lower scores that were statistically significant. It was also assessed that the efficacy of the JointStem treatment showed statistically significant improvement in comparison with the placebo injection group (each p value = 0.0043, 0.0307, 0.0018). KOOS (Knee injury and Osteoarthritis Outcome Score) was evaluated by the subgroup items such as symptoms, pain, functions in daily living, sports and recreation, and scores increased in all the subgroup items in comparison with the placebo injection group. The efficacy of the JointStem treatment group showed statistically significant improvement in all the subgroup items (each p value = 0.0002, 0.0002, 0.0017, 0.0003, 0.0060).

For SF-36, which evaluates quality of life, both physical health score and mental health scores increased significantly in the JointStem injection group, and the efficacy of treatment also showed statistically significant improvements (each p value = 0.0084, 0.0038). IKDC score, which evaluates knee function and activity evaluation, also increased higher in the JointStem injection group, and the efficacy of treatment showed statistically significant improvement ( $p < 0.0001$ ).

From the X-ray evaluation, three patients in the JointStem injection group improved from K-L grade 3 to 2 (two patients) or from K-L grade 4 to 3 (one patient), and 104 patients remained the same grade as before the JointStem injection. However, no patient improved in the placebo injection group.

The MRI analysis showed that the number and ratio of subjects whose cartilage defect depth, cartilage defect surface size, bone marrow lesion size, and subchondral attrition and subchondral cyst size and cartilage cyst were improved or maintained in the Medial Tibia and Medial WB Femur, which are the major lesions of the knee joint, were higher in the JointStem injection group than in the placebo group.

It was confirmed that the number of days that the patients took the same pain relief medicine, and the total dosage of the medicine were less in the JointStem injection group than those in the placebo injection group. The comparison between the two groups showed statistically significant difference (each p value = 0.0338, 0.0008), so the study confirmed that JointStem injection reduced the number of days that the patients took pain relief medicine and the total dosage of the medicine.

For the safety analysis, there was no significant adverse event that was related to JointStem. In addition, no specific matters were found from the JointStem injection group in comparison with the placebo injection group. Since the JointStem clinical trial started from 2008, there has been no case of tumors related to the administration of JointStem.

In addition, the long-term tracking MRI analysis of the previous JointStem phase 2 clinical trial noted that cartilage defects reduced more after two or three years than after six months, and that the knee cartilage showed more improvement.

Chairman of Nature Cell and Lead Researcher of JointStem Development, Dr. Jeong-Chan Ra said, "Thank you to everyone who helped us on the success of JointStem phase 3 clinical trial. I believe this is the outcome from continuous faith and prayer. Do your best and pray for God's answer."

Dr. Ra also added, "We are now preparing for quality controls and GMP facilities, which are other requirements for a new drug approval. We will soon apply for the approval of JointStem as a new drug within the next few months."

References:

What is JointStem?

JointStem is the world's first stem cell therapy for patients with severe osteoarthritis of the knee which uses autologous adipose tissue-derived mesenchymal stem cells (AdMSC) that improves knee joint function and reduces pain. Furthermore, it regenerates and improves knee cartilage. Unlike other existing similar drugs for degenerative arthritis, JointStem does not require repetitive injections periodically, but requires only one injection of one dose. It is an innovative therapy without surgery. Osteoarthritis is an irreversible disease and cannot be cured naturally, so an artificial joint replacement is required eventually. But JointStem can delay the deterioration of osteoarthritis or prevent it, so it is expected that JointStem will be a new therapy with huge benefits at low risks.

Clinical Trial History

JointStem began its development from 2005, and the clinical trial phase 1, 2 (approved in 2008), phase 2b (approved in 2014) and phase 3 have been performed. Phase 3 of the study was approved in January 2019 after the review of Central Pharmacy Review Committee of Korean Ministry of Food and Drug Safety. All 13 hospitals including Kyung Hee University Hospital at Gangdong and a total of 252 patients participated in the phase 3 clinical trial. In the United States, JointStem phase 2 was approved by Food and Drug Administration and was performed successfully. Patients are now being recruited for the phase 2b/3a of the clinical trial.

JointStem phase 3 clinical trial was performed for severe patients with Kellgren-Lawrence (K-L) grade 3. The primary objective of the clinical trial was to confirm the safety and efficacy of JointStem injection for the pain reduction of osteoarthritis and the improvement of knee cartilage function, and, to prove the efficacy of JointStem, WOMAC (Osteoarthritis Index) and VAS (Pain Index) were used as the primary evaluation variables. The difficulty level of this clinical trial was very high requiring to obtain the statistical significance for both primary evaluation variables. The placebo drug was a mixture of a stabilizer autologous serum and a suspending normal saline from JointStem excluding the autologous adipose tissue derived mesenchymal

stem cells.

The first patient was enrolled on June 13, 2019 and 334 patients were screened, and 261 patients were randomly assigned. JointStem or the placebo drug were injected into the 252 patients out of the 261 assigned, and the 252 patients were included in this clinical study report for statistical analysis.

For inquiries, please contact:

Dr. Sung Keun Kang, Vice President of Biostar Stem Cell Research Institute (02-6978-9601)/Jae Uk Shim, Vice President (02-6978-9268)

Jane Shin  
Stemcell Bio  
[email us here](#)

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