

Overview of study given by Gloria @ Artemis:

This is a multi-center, randomized, double-blind, placebo-controlled, parallel-group study in patients with hip OA. Approximately 440 patients will be randomized to one of two treatment groups (1:1) and treated with a single IA injection of either 32 mg FX006 or normal saline. FX006 or saline placebo will be administered as a single IA injection with a 12-week follow-up period in the double-blind phase. Patients eligible for the second injection in the open-label phase at Week 12 will receive an open-label injection of FX006 at Week 12 and return for follow-up visits at Weeks 16, 20, and 24. These patients will complete the study at Week 24. Patients that are not clinically indicated for a second injection at Week 12 will return to the clinic at Weeks 16, 20, and 24 and will receive an open-label injection of FX006 at the first evaluation where the patient has been determined to meet all criteria. Patients will then return for follow-up visits every 4 weeks for 12 weeks post second injection and will complete the study 12 weeks post second injection (e.g., Week 24, 28, 32, or 36 depending on when the patient receives the open-label injection). Patients who are not eligible for a second injection after evaluation at Weeks 12, 16, 20, and 24 will complete the study at the Week 24 visit and complete the End of Study (EOS) assessments.

Screening subjects will need a screening hip X-ray and will also have a week 12 hip x-ray. Study medication will be administered under fluoroscopy guidance.